AdvaMed
The Medtech Association

April 7, 2026

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Medical Devices; Exemptions from Premarket Notification: Class II Devices; Request for Comments, Docket Number FDA-2026-N-0232

To Whom It May Concern:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to submit comments in response to the Federal Register Notice regarding the proposed list of device exemptions from Premarket Notification.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical technology. AdvaMed's member companies range from the largest to the smallest medical product innovators and manufacturers. AdvaMed's member companies produce innovations that transform health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

AdvaMed appreciates the Food and Drug Administration (FDA or "Agency") for publishing this notice containing a list of devices that FDA determines no longer require a report under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or FDCA). We support FDA's continued efforts to implement the 21st Century Cures Act by appropriately expanding exemptions from premarket notification for Class II devices where a 510(k) submission is not necessary to provide reasonable assurance of safety and effectiveness. Properly tailored exemptions can reduce administrative burden, promote regulatory efficiency, and allow both FDA and industry to focus resources on higher-risk technologies, while maintaining robust post-market oversight and other applicable regulatory controls. We respectfully submit for your consideration our comments in response to the devices listed in the notice, as well as our additional recommendations for exemption.

Support for Proposed Exempt Class II Devices Subject to General Limitations

AdvaMed fully supports FDA's list of proposed exempt Class II devices subject to general limitations outlined in Table 1.

Removing Categorical Restrictions on *In Vitro* Diagnostics (IVDs) in .9 Regulations to Align with the Statutory Framework

Congress granted FDA authority in the FDCA to regulate medical devices through a clear and deliberate risk-based statutory framework. A central pillar of this scheme is that the level of regulatory control must be directly proportional to the specific risk a device poses to patients. To achieve this, Congress separated medical devices into three Classes (I, II, and III) based on escalating risk.

The statute requires that devices are classified based on an individualized assessment of their "safety and effectiveness". The text of the FDCA, specifically 21 U.S.C. § 360c, consistently focuses on the risk profile of the device under review, based on its unique characteristics, technology, and intended use.

Contrary to the individualized, risk-based system Congress designed in the FDCA, FDA's regulations outlining the limitations on premarket notification exemptions impose a blanket prohibition that functions as an automatic and absolute disqualifier for certain categories of IVDs to be exempt from premarket notification requirements. At issue are identical provisions, found across Parts 862 through 892 of Title 21 of the Code of Federal Regulations, triggered by an IVD inclusion in one of these categories (hereinafter referred to as the .9 regulations). These categories include, among others, tests intended for near-patient settings, identifying a microorganism directly from specimen, assessing the risk of cardiovascular diseases, and use in diabetes management. These categories codify FDA's understanding of risk in 1998 and, based on the increased understanding of these technologies over time, we encourage the Agency to revise the categorical exemption approach.

The underlying statute exempts Class I and II medical devices, including IVDs, from premarket notification with limited exceptions because general controls (e.g., quality management system regulations and postmarket regulations) provide sufficient regulation to mitigate the risk of devices. Specifically, authority granted by the FDA Modernization Act of 1997 (FDAMA), which amended Section 510 of the FDCA, states that the general exemption from premarket notification "does not apply to any Class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any Class I device that presents a potential unreasonable risk of illness or injury." This statutory text is critical because it clearly specifies a device-specific inquiry based on the intended use of a particular device and the potential risk it presents. Despite this statutory change, in 1998, FDA instituted blanket limitations for IVDs.[1] Notably, the Agency solely adopted this approach for IVDs. IVDs, devices primarily used outside the body, do not inherently possess a higher risk than other device types.

FDA's primary justification for this regulatory change in 1998 was that a device with a different intended use than a generic, already approved device type does not have the same evidence-

[1] Medical Devices; Exemption from Premarket Notification and Reserved Devices; Class I 63 Fed. Reg. 63222, 63223 (Nov. 12, 1998).

backed assurance of safety and effectiveness and therefore must undergo premarket review.[2] That is, devices for whom the risk profile is not well studied and understood must adhere to the premarket notification requirements in order to minimize unnecessary risk.

In the nearly three decades since the regulation was issued, we have a much deeper understanding of these IVDs. These blanket limitations established an inflexible application of the exemption provisions to the regulation of IVDs which created a level of regulatory oversight that is no longer necessary because of the increased insights into the risk of these devices. Subjecting low-risk IVDs to unnecessary premarket review when significant technological advances and the practice of medicine have evolved creates undue burden on developers as well as the Agency and unnecessary delays for patient access. Regulatory resources at a time of unprecedented innovation creates a constant challenge and an ever-increasing workload for the Agency combined with newer novel product areas (e.g., digital, AI). FDA's pre-market review resources need to be used efficiently and reflect the increased understanding of these technologies that have come from time and experience. After nearly three decades, we encourage the Agency to eliminate the blanket IVD limitations of exemption to align with the statute and remove unnecessary regulatory barriers on IVD devices.

Near-Patient Testing Categorical Restriction Outdated and Inconsistent with Statutory Framework

We believe revising the categorical exemption approach could positively impact the development of near-patient tests. Blanket limitations enacted nearly three decades ago, despite significant technological advancements, serve as a deterrent to point-of-care (POC) or near-patient testing innovation by imposing a higher bar to market than IVDs for centralized testing. We strongly support the Agency's initiative Home as a Healthcare Hub which focuses on "reimagin[ing] the home as an integral part of the health care system, by incorporating, in the home, new and existing medical devices that promote health and wellness in people's lives, potentially leading to a longer, higher-quality life for all"[3] Within the context of increasing accessibility, revising the categorical exemptions could further advance bringing more POC tests to patients outside hospital settings, which can greatly benefit patient and public health.

Throughout Title 21, identical limiting language appears requiring a test that would otherwise be low-risk and exempt from pre-market review—and could therefore be available by adhering to FDA general controls without additional premarket FDA review— to go through FDA review based on the intended use setting as understood by FDA in the late 1990's.

FDA's factual rationale for the near-patient testing categorical restriction in the .9 regulations, rooted in its experience with the technology of the 1990s, is demonstrably obsolete today. Over the past nearly 30 years, the risks of user error and lack of quality control that were plausible

[2] Medical Devices; Exemption from Premarket Notification and Reserved Devices; Class I 63 Fed. Reg. 63222, 63223 (Nov. 12, 1998).

[3] Home as a Health Care Hub. https://www.fda.gov/medical-devices/home-health-and-consumer-devices/home-health-care-hub

then have been addressed by more than two decades of revolutionary technological progress. Today's POC diagnostics bear little resemblance to their predecessors, incorporating sophisticated advancements in automation, microfluidics, integrated quality control, and data connectivity that ensure their accuracy and reliability. Multiple studies have validated that the accuracy of modern POC devices is equivalent to laboratory testing, shattering the outdated notion that testing near-the-patient necessarily involves a trade-off in performance and quality. The passage of time has ushered in a significant evolution in technology coupled with increased FDA understanding that shifts the balance of risk.

As part of our itemized list below, we offer specific examples of IVDs that we believe should be exempt from premarket review requirements notwithstanding that they may fall into one of these outdated categories such as "near-patient testing" or identifying microorganisms directly from patient specimens, diabetes management, or assessing cardiac risk. We focus our recommendations on whether the criteria in the statute and the *Federal Register* notice are met. These categorical prohibitions deprive FDA of an ability to make risk benefit determinations. What we ask for is a more nuanced approach to risk/benefit determinations, which will also enable FDA to focus limited resources in a risk-centered manner.

Statutory Focused Criteria Used for Developing Recommendations for 510(k) Exemption

In developing the list of recommendations, we rely upon the statutory language, which states that the exemption from premarket notification does not apply to a "Class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any Class I device that presents a potential unreasonable risk of illness or injury" (21 U.S.C. § 360(l) or in the case of a Class II device "no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness" (21 U.S.C. § 360(m). As discussed, if a particular device, taking into account intended use and technological features, does not meet this threshold, it is eligible for 510(k) exemption pursuant to the statute.

In addition, we also evaluated the criteria in the *Federal Register* notice, that "(1) the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification." FDA also notes that the limitations in the .9 regulations could also limit devices that could be exempt from the 510(k) requirement. We include in our recommendation devices, including IVDs, that meet the statutory threshold and meet the criteria enumerated in the *Federal Register* notice, with the notable exception that we do not exclude from our list IVDs that might fall within one or more of the IVD-specific.9 categorical limitations.

We appreciate the opportunity to provide feedback and look forward to continued collaboration with FDA to support regulatory efficiency. Please also refer to the accompanying tables, which are separated and color coded for convenience. Please feel free to contact Jamie with any questions related to *in vitro* diagnostic devices and Geeta for all other devices.

Sincerely,

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ADVAMED'S COMMENTS TO TABLE 2 IN FR NOTICE: FDA'S PROPOSED EXEMPT CLASS II DEVICES SUBJECT TO GENERAL LIMITATIONS		
REGULATION, DEVICE TYPE, PRODUCT CODE	**PROPOSED CHANGE TO THE PARTIAL LIMITATIONS**	**RATIONALE FOR PROPOSED CHANGE**
§ 870.5800 Sleeve, limb, compressible, JOW	We recommend that these devices remain Class II, requiring premarket notification [510(k)]	We advise against eliminating the 510(k) requirement as it would remove a critical safeguard that ensures essential evidence, testing, and performance standards. Intermittent pneumatic compression (IPC) devices and compressive sleeve devices are intended to prevent venous thromboembolism (VTE), a serious and potentially fatal condition that includes pulmonary embolism (PE) and deep vein thrombosis (DVT). The U.S. Centers for Disease Control and Prevention estimates that 60,000–100,000 Americans die from VTE each year, with many more experiencing significant long-term complications. Adverse events reported to the FDA include tissue injury, bruising, skin irritation, and nerve damage. Given these known risks, it is essential that these devices continue to undergo rigorous FDA premarket review before being commercially marketed in the United States (U.S.) to ensure that product performance and compatibility are evaluated by FDA. FDA's proposed partial limitations (#3) includes devices indicated for the foot and FDA's proposed partial limitations (#4) specifies the exemption applies to devices within the pressure range of 20–120 mm Hg. Published literature indicates that foot compression requires substantially higher pressures—often 130 mm Hg or more—compared to calf compression. Therefore, the proposed exemption conditions may result in ineffective treatment for devices indicated for the foot. Removing FDA premarket oversight may accelerate the entry of low-quality devices that do not perform as intended, undermining U.S. innovation and threatening the high standards currently maintained through the FDA clearance process. This shift would erode the quality of care delivered in U.S. healthcare

AdvaMed's Comments to Table 2 in FR Notice: FDA's Proposed Exempt Class II Devices Subject to General Limitations		
Regulation, Device Type, Product Code	**Proposed Change to the Partial Limitations**	**Rationale for Proposed Change**
		settings and disadvantage U.S. manufacturers who remain subject to stringent regulatory requirements both domestically and abroad. Additionally, eliminating FDA premarket review would have far-reaching implications for reprocessed sleeves and device–sleeve compatibility. Without regulatory controls, third-party manufacturers could introduce sleeves that are non-compatible with existing IPC systems, raising serious safety and efficacy concerns in this vulnerable patient population. An influx of substandard or incompatible products in hospitals and home-care settings would increase patient harm, drive higher downstream costs (including complications, wound care, and rehospitalizations), and damage the trust of patients, clinicians, and payers. The market is already seeing a proliferation of consumer-oriented IPC devices marketed for non-DVT indications. These devices often use pressure profiles that differ from those needed for DVT prevention. Allowing exemptions would blur the regulatory line between therapeutic IPC systems used for VTE prevention and consumer wellness devices, creating confusion and risks for patients and providers. We recommend FDA maintain the requirement for 510(k) premarket review for all intermittent pneumatic compression devices intended for clinical use in both home and hospital settings. Removing this important regulatory safeguard poses unacceptable risks to patient safety, product integrity, and the overall quality of U.S. healthcare.

ADVAMED'S COMMENTS TO TABLE 2 IN FR NOTICE: FDA'S PROPOSED EXEMPT CLASS II DEVICES SUBJECT TO GENERAL LIMITATIONS		
REGULATION, DEVICE TYPE, PRODUCT CODE	**PROPOSED CHANGE TO THE PARTIAL LIMITATIONS**	**RATIONALE FOR PROPOSED CHANGE**
§ 880.5570, Container, sharps, MKK	Recommend revising as follows: "Exemption is limited to devices that meet the following conditions: 1. Device is intended for single use; ~~2. Device is intended to be used in a healthcare setting;~~ 3. Device is intended to contain only sharps for disposal; 4. Device does not include software or electronic components; and …"	Recommend removing the required condition/limitation that the device must be intended for use in a healthcare setting. Many sharps containers are used in general settings outside of a healthcare setting. The design and intended function of these products do not change based on the use setting. As such, we recommend deleting the suggested text to maximize the benefit and applicability of exempting the MMK product code.

ADVAMED'S PROPOSED EXEMPT CLASS II (NON-IVD) DEVICES SUBJECT TO GENERAL LIMITATIONS		
REGULATION, DEVICE NAME	**PRODUCT CODE(S)**	**RATIONALE FOR EXEMPTION**
§ 866.2900, Microbiological specimen collection and transport device	JTW	866.2900 is classified as Class I, however several product codes within this regulation require 510(k). More specifically, urine collection/transport devices under JTW product code require a 510(k), which is inconsistent with most other product codes related to urine microbiology that are Class I and 510(k) exempt (e.g., JXA). As such we recommend making the JTW product code Class I exempt to be consistent with other similar products in the space.
§ 870.1130, Non-Invasive Blood Pressure Systems	DXN	FDA is currently proposing to exempt Blood Pressure Cuff (870.1120, DXQ product code). We recommend also exempting Non-Invasive Blood Pressure Systems (870.1130, DXN) as it is a very similar device to DXQ devices. Both are non-invasive devices under the cardiovascular panel with comparable risk profiles. Product code DXN consists of devices with a well- established safety profile with well governed and well-defined regulatory standards (e.g., 81060-2, -3, -5, IEEE std 1708 and more. Additionally, FDA's guidance "Non-Invasive Blood Pressure (NIBP) Monitor Guidance" applies equally to devices in the DXQ and DXN product codes.
§ 872.3200, Resin Tooth Bonding Agent	KPE	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards (including ISO 10993) and design controls; ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
§ 872.3250, Calcium Hydroxide Cavity Liner	EJK	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards (including ISO 10993) and design controls: ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

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REGULATION, DEVICE NAME	**PRODUCT CODE(S)**	**RATIONALE FOR EXEMPTION**
§ 872.3275, Dental Cement	EMA MZW NEA	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards (including ISO 10993) and design controls: ISO 9917-2 Second edition 2010-04-15 Dentistry - Water-based cements - Part 2: Resin-modified cements ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry ANSI ADA Specification No.30 – Dental Zinc Oxide-Eugenol and Zinc Oxide Non-Eugenol Cements: 2000 (Reaffirmed 2005) ISO 9917-1 Second edition 2007-10-01 Dentistry-- Water-based cements - Part 1: Powder/liquid acid-base cements ADA/ANSI Specification No.96 – Dental Water-Based Cements: 2000 (Reaffirmed 2005) ISO 3107 Third edition 2004-10-01 Dentistry - Zinc oxide/eugenol and zinc oxide/non-eugenol cements – Third Edition ISO 3107 Fourth edition 2011-03-01 Dentistry – Zinc oxide/eugenol and zinc oxide/non-eugenol cements FDA Guidance Document: Dental Cements - Premarket Notification; Final

ADVAMED'S PROPOSED EXEMPT CLASS II (NON-IVD) DEVICES SUBJECT TO GENERAL LIMITATIONS		
REGULATION, DEVICE NAME	**PRODUCT CODE(S)**	**RATIONALE FOR EXEMPTION**
§ 872.3660, Impression Material	ELW	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards (including ISO 10993) and design controls: FDA guidance "Dental Impression Materials- Performance Criteria for Safety and Performance Based Pathway" (2024) ISO 13716 First edition 1999-05-01 Dentistry - reversible-irreversible hydrocolloid impression material systems ADA/ANSI Specification No.19 Dental -Elastomeric Impression Material:2004 ISO 4823 Third edition 2000-12-15 Dentistry - Elastomeric impression materials - Third Edition ISO 4823:2000 Technical Corrigendum Published 2004-07-15 Dentistry -Elastomeric impression materials Technical Corrigendum 1 ISO 4823 Third edition 2000-12-15 Amendment 1 2007-07-01 Dentistry - Elastomeric impression materials Amendment 1 ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry ADA/ANSI Specification No.18 Alginate Impression Materials: 1992 ISO 1563 Second edition 1990-09-01Dental alginate impression material ISO 1564 Second edition 1995-11-01 Dental aqueous impression materials based on agar

ADVAMED'S PROPOSED EXEMPT CLASS II (NON-IVD) DEVICES SUBJECT TO GENERAL LIMITATIONS		
REGULATION, DEVICE NAME	**PRODUCT CODE(S)**	**RATIONALE FOR EXEMPTION**
§ 872.3690, Tooth Shade Resin Material	EBF	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards and design controls: ISO 4049 Fourth edition 2009-10-01 Dentistry - Polymer-based restorative materials ANSI ADA Specification No.80 2001 (Reaffirmed 2007) Dental Materials - Determination of Color Stability ANSI ADA Specification No.53 Polymer Based Crowns and Bridge Resins:1999 (Reaffirmed 2008) ADA/ANSI; ISO 10477 Second edition 2004-10-01 Dentistry - Polymer-based crown and bridge materials ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry FDA Guidance: Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff
§ 872.3750, Bracket Adhesive Resin and Tooth Conditioner	DYH KZP	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards design controls: ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

ADVAMED'S PROPOSED EXEMPT CLASS II (NON-IVD) DEVICES SUBJECT TO GENERAL LIMITATIONS		
REGULATION, DEVICE NAME	**PRODUCT CODE(S)**	**RATIONALE FOR EXEMPTION**
§ 872.3765, Pit and Fissure Sealant and Conditioner	EBC	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards and design controls: ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry ADA/ANSI Specification No.39 - Pit and Fissure Sealants: 2006 ISO 6874 Second edition 2005-08-15 Dentistry - Polymer-based pit and fissure sealants FDA Guidance Document: Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff
§ 872.3770, Temporary Crown and Bridge Resin	EBG	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards and design controls: ANSI ADA Specification No.80 2001 (Reaffirmed 2007) Dental Materials - Determination of Color Stability ANSI ADA Specification No.53 Polymer Based Crowns and Bridge Resins:1999 (Reaffirmed 2008) ADA/ANSI ISO 10477 Second edition 2004-10-01 Dentistry - Polymer-based crown and bridge materials

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REGULATION, DEVICE NAME	**PRODUCT CODE(S)**	**RATIONALE FOR EXEMPTION**
		ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
§ 872.4120, Bone Cutting Instrument and Accessories	DZH DZI DZJ KMW MXF	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards and design controls: ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry ISO 5832-1:2007 Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel ISO 5832-9:2007 Implants for surgery - Metallic materials - Part 9: Wrought high nitrogen stainless steel ISO 7785-1 Second edition 1997-08-01 Dental handpieces -- Part 1: High-speed air turbine handpieces ISO 7785-2 Second edition 1995-08-01 Dental handpieces -- Part 2: Straight and geared angle handpieces ISO 11498 First edition 1997-02-15 Dental handpieces: Dental low-voltage electrical motors ISO 9168 Third edition 2009-07-15 Dentistry - Hose connectors for air driven dental handpieces
§ 872.5470, Orthodontic Plastic Bracket	DYW NJM NLC	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards and design controls:

ADVAMED'S PROPOSED EXEMPT CLASS II (NON-IVD) DEVICES SUBJECT TO GENERAL LIMITATIONS		
REGULATION, DEVICE NAME	**PRODUCT CODE(S)**	**RATIONALE FOR EXEMPTION**
	NXC OYH	ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
§ 872.5500, Extraoral Orthodontic Headgear	DZB	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards and design controls: ISO 5832-1:2007 Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel ISO 5832-9:2007 Implants for surgery - Metallic materials - Part 9: Wrought high nitrogen stainless steel
§ 872.6070, Ultraviolet Activator for Polymerization	EBZ	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards and design controls: ADA/ANSI Specification No.48 Visible Light Curing Units; FDA Guidance Document: Dental Curing Lights - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff
§ 872.6080, Airbrush	KOJ	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards and design controls: ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

ADVAMED'S PROPOSED EXEMPT CLASS II (NON-IVD) DEVICES SUBJECT TO GENERAL LIMITATIONS		
REGULATION, DEVICE NAME	**PRODUCT CODE(S)**	**RATIONALE FOR EXEMPTION**
§ 872.6660, Porcelain Powder for Clinical Use	EIH	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices. The devices should be exempt subject to consensus standards and design controls: ANSI ADA Specification No.38 2000 (Reaffirmed 2010) Metal-Ceramic Dental Restorative Systems ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry ANSI ADA Specification No.69 Dental Ceramic:2010; ISO 9693-2012 Dentistry - Compatibility testing - Metal-ceramic systems ISO 6872 Third edition 2008-09-01 Dentistry - Ceramic materials
§ 880.5025, Container, IV	KPE	Product code KPE contains multiple devices; including IV container devices and associated accessories and components such as IVA seals. IVA seals are distinct in form, function, risk and failure modes from IV container devices. It is recommended that FDA exempt from premarket notification IVA seals intended for use as tamper evident accessories to IV container devices. IVA seals intended solely for tamper-evident purposes fit the criteria for Class I exempt accessories; • They are not used to support or sustain human life • They do not pose a potential unreasonable risk of injury • General controls alone are sufficient to provide reasonable assurance of safety and effectiveness.

ADVAMED'S PROPOSED EXEMPT CLASS II (NON-IVD) DEVICES SUBJECT TO GENERAL LIMITATIONS		
REGULATION, DEVICE NAME	**PRODUCT CODE(S)**	**RATIONALE FOR EXEMPTION**
§ 890.5150(b), Transport, patient, powered	ILK	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices: Factor (1): Across FDA's MAUDE, Medical Device Recalls, and Warning Letter databases, there is no evidence of a significant safety signal or pattern of false or misleading claims for devices under § 890.5150(b). The data indicates a low risk profile with risks adequately managed under existing controls. o Zero serious injury or death events were identified for Product Code ILK over the 2016–2026 period. o One MDR (Report MW5154444) involving patient injury was associated with the Bruno Elan SRE 3050, which aligns more closely with § 890.5150(a) (product code PCD) than § 890.5150(b). Note – PCD is exempt from pre-market notification o Two manufacturer-initiated recalls from 2017 (Omega Incline Platform Lift; Savaria Stairfriend) - both associated with § 890.5150(a), Product Code PCD, were due to mechanical integrity concerns with no adverse events and related to manufacturing issues for powered stairway chair lifts, not the devices under § 890.5150(b). Factor (2): Safety and performance for devices under § 890.5150(b) are appropriately managed by general controls and FDA-recognized consensus standards, without the need for routine premarket review. Applicable standards collectively ensure electrical/mechanical safety, EMC, software reliability (if present), usability, and risk management consistent with state-of-the-art practices. Factor (3): Any changes to devices under 21 CFR § 890.5150(b) that might impact safety or effectiveness will either be easy for users to notice or will not significantly increase risk. Internal changes are managed through standard design change controls (21 CFR § 820.30) and risk management (ISO 14971). If a change does raise the device's risk, it would fall under the limitations of 21 CFR § 890.9 and require a 510(k). Clear and prominent labeling required by 21 CFR § 801 and ISO 15223-1 ensures that any changes affecting use or safety are easy for users to identify. Overall, changes to § 890.5150(b) devices are either readily detectable or do not materially increase risk, and any higher risk change is already captured under existing regulatory limits.

ADVAMED'S PROPOSED EXEMPT CLASS II (NON-IVD) DEVICES SUBJECT TO GENERAL LIMITATIONS		
REGULATION, DEVICE NAME	**PRODUCT CODE(S)**	**RATIONALE FOR EXEMPTION**
		Factor (4): ○ The intended use across legally marketed § 890.5150(b) devices is consistent and well understood. ○ Technology is mature, and changes over time have not introduced new safety or effectiveness questions that would necessitate routine premarket review. ○ Potential risks (e.g., mechanical failure, instability, entrapment, electrical faults) are well characterized and adequately controlled through design controls, verification/validation, labeling, and post market surveillance. Additionally, several device types with comparable intended use and risk are already exempt from 510(k), including: ○ § 890.5150(a) (Powered Stairway Chair Lift) ○ § 880.6900 (Stretcher, Hand Carried) ○ § 890.3690 (Stretcher, Wheeled, Powered) Devices under § 890.5150(b) share common features and risk profiles with these categories. Exempting § 890.5150(b) would be consistent with FDA's risk-based regulatory approach, focusing premarket resources on higher risk devices while maintaining safety via general controls and applicable special/consensus standards.

ADVAMED'S PROPOSED EXEMPT CLASS II (NON-IVD) DEVICES SUBJECT TO GENERAL AND PARTIAL LIMITATIONS		
REGULATION, PRODUCT CODE, DEVICE NAME	**PROPOSED PARTIAL LIMITATIONS**	**RATIONALE FOR PROPOSED CHANGE**
§ 870.2300, MSX, System, network and communication, physiological monitors	FDA should consider a 510(k) exemption for MSX-classified devices that meet all of the following conditions: 1. Alarm Priority Configuration: Alarm priority levels, escalation rules, and clinical significance are entirely configured by healthcare professionals or healthcare institutions, not predefined by the manufacturer. 2. No Independent Clinical Interpretation: ○ The device does not assign clinical meaning, risk stratification, or diagnostic significance to physiological data. ○ The device does not determine alarm severity based on physiologic signal analysis beyond receiving alarm states from upstream devices. 3. No Autonomous Clinical Action: ○ The device does not initiate therapy, suppress primary device alarms, or perform closed-loop control. ○ The device does not override alarm generation from the source medical device. 4. Transparent, Constrained Functionality:	Devices meeting the criteria described within the proposed partial limitations- referred to as "Secondary Alarm Systems" - currently classified under product code MSX, are appropriately distinguished as a narrower subset presenting a more bounded and predictable risk profile than other MSX-classified technologies that independently interpret physiologic data or execute autonomous clinical actions. Secondary Alarm Systems function as configurable secondary alarm, communication, and workflow tools, rather than as systems that independently drive, determine, or execute clinical decisions. These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices: <u>Factor (1):</u> Secondary Alarm Systems do not have a significant history of false or misleading claims, nor do they present inherent risks associated with device design or materials that would necessitate continued premarket notification. A 10-year retrospective review of FDA post-market sources - including the MAUDE database, the recalls database, and FDA safety communications identified a limited number of reported malfunctions associated with Secondary Alarm Systems (reports were from devices cleared under 5 specific 510(k) submissions, which can be provided upon request). In each instance, manufacturer follow-up reporting indicated that the device appeared to perform as intended upon examination. Importantly, no recalls and no FDA safety communications were identified for this device subset. The available post-market data demonstrates that issues are infrequent, non-systemic, and not attributable to independent clinical interpretation or autonomous device action, supporting the conclusion that Secondary Alarm Systems represent a distinct, lower-risk subset within Class II

ADVAMED'S PROPOSED EXEMPT CLASS II (NON-IVD) DEVICES SUBJECT TO GENERAL AND PARTIAL LIMITATIONS		
REGULATION, PRODUCT CODE, DEVICE NAME	**PROPOSED PARTIAL LIMITATIONS**	**RATIONALE FOR PROPOSED CHANGE**
	○ The device operates within manufacturer-validated constraints and guardrails. ○ The intended use explicitly states that clinical responsibility for alarm prioritization resides with the healthcare provider or institution.	MSX devices. Factor (2): The characteristics necessary for the safe and effective performance of Secondary Alarm Systems are well established (e.g., FDA-recognized alarm system consensus standards). These systems rely on mature, well-understood functions - secondary alarm aggregation, routing, prioritization, and notification - that are already present in legally marketed physiological monitoring systems. In routine clinical practice, healthcare professionals configure alarm limits, priorities, and escalation pathways based on institutional protocols and patient populations without triggering new premarket submissions. FDA has previously recognized that secondary alarm and notification systems with similar functional characteristics may be safely regulated without premarket notification. For example, FDA classified Continuous Glucose Monitor (CGM) Secondary Alarm Systems (21 CFR § 862.1350) as Class II devices exempt from premarket notification, based on the determination that such systems provide secondary notification without independently driving therapy or replacing primary monitoring or clinical decision-making. Secondary Alarm Systems as defined herein present a parallel functional and risk profile, reinforcing that the characteristics necessary for safe and effective performance are well established. Factor (3): Changes to Secondary Alarm Systems that could affect safety or effectiveness would either be readily detectable by users prior to causing harm, or would not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment. Secondary Alarm Systems operate in an open-loop, human-in-the-loop configuration and explicitly exclude physiologic closed-loop control. Any changes to alarm prioritization logic, configuration parameters, or

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		notification workflows remain subject to user review, routine testing, and institutional governance before influencing patient care. Because these systems do not independently interpret physiologic data or initiate clinical action, modifications do not introduce latent risks that would require premarket review to detect. Factor (4): Changes to Secondary Alarm Systems are not likely to result in a change in device classification. The intended use and fundamental technological characteristics remain limited to secondary alarm aggregation and user-configured prioritization within the MSX framework. Modifications to interfaces, configuration options, or notification pathways do not alter the core function of the device or elevate it into a higher-risk category involving autonomous clinical decision-making or therapy control. Accordingly, such changes would not be expected to warrant reclassification.
§ 870.2910, DRG, Transmitter and receiver, physiological signal	FDA should consider a 510(k) exemption for DRG classified devices that meet all of the following conditions: 1. Passive Signal Transmission Only: ○ The device transmits, receives, or relays physiological signals or associated metadata without altering the underlying signal content. ○ The device does not modify waveform morphology, derive new parameters, or perform signal processing that changes clinical meaning. 2. No Independent Clinical Interpretation	Devices meeting the criteria described within the proposed partial limitations—referred to as "Passive Physiological Signal Transmission Systems"—represent a distinct and well-bounded subset of devices currently classified under product code DRG. These systems function as infrastructure components that enable the transport and availability of physiological data, rather than systems that interpret, transform, or act upon that data. This subset is fundamentally different from higher-risk DRG implementations that may incorporate signal processing, alarm generation, or device control. Passive Physiological Signal Transmission Systems operate as transparent conduits, preserving the fidelity and meaning of physiological signals as generated by upstream medical devices.

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	○ The device does not assign clinical interpretation, diagnostic conclusions, or risk stratification to transmitted data. ○ The device does not generate alarms or clinical notifications based on analysis of physiological signals. 3. No Control of Source or Downstream Devices ○ The device does not control, adjust, or influence the operation of connected medical devices. ○ The device does not initiate therapy, modify alarm states at the source, or perform closed-loop control. 4. Data Integrity and Transparency Constraints ○ The device maintains traceability of transmitted data, including source identification and time synchronization where applicable. ○ The device operates within validated performance specifications for latency, reliability, and data integrity. ○ The labeling clearly states that the device is not intended for primary diagnosis or clinical decision-making without confirmation from the source device.	

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§ 876.5980, FEG, Gastrointestinal Tube and Accessories	Subject to FDA-recognized standards and design controls: AAMI/ANSI ID54:1996/(R)2005 Enteral feeding set adapters and connectors.	Devices classified under product code FEG are based on well-understood technologies that have remained consistent over decades of clinical use. The key safety and performance attributes—such as biocompatibility of patient-contacting materials, structural integrity, sterility, and lumen patency—are comprehensively addressed through established, widely recognized standards and routine verification methods. These devices do not incorporate novel technologies, or complex design elements that would introduce new or uncertain risks. Because the device design, manufacturing processes, and associated risk profile are stable, predictable, and fully characterized, the existing general and special controls are sufficient to ensure safety and effectiveness without the need for a premarket notification.
§ 876.5980, KDH, Gastrointestinal Tube and Accessories	Subject to FDA-recognized standards and design controls. AAMI/ANSI ID54:1996/(R)2005 Enteral feeding set adapters and connectors.	Devices classified under product code KDH are based on well-understood technologies that have remained consistent over decades of clinical use. KDH devices employ well-established, low-risk technology. The devices are, passive, single-use, non-implantable and made of well-characterized materials. This aligns with FDA's criteria for 510(k) exemption which includes technologies that are mature and predictable. Their materials of construction (e.g., PVC) have well-established biocompatibility. Their performance requirements (e.g., tube patency, structural integrity, fluid flow) are also well-understood. Sterility and packaging are validated through processes outlined in FDA-recognized consensus standard ISO 11135/11137. There are no complex failure modes requiring FDA premarket review.

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§ 876.5980, PNR, Gastrointestinal tube and accessories.	Oral Feeding Syringe - The device labeling states that the syringes are intended for oral feeding only - The device design does not incorporate an ENFit or another enteral specific connector - The device is not intended to connect to a feeding tube, extension set, infusion/enteral pump or gastrointestinal access device for administration via gastric, nasogastric, or post pyloric routes. - The labeling includes the necessary warnings and cautions appropriate to the device's restricted intended use for oral feeding applications.	Oral feeding syringes are designed exclusively for oral administration and do not incorporate an ENFit or another enteral specific connector. These devices are not intended to connect to a feeding tube, extension set, infusion/enteral pump or gastrointestinal access device for administration via gastric, nasogastric, or post pyloric routes. Additionally, FDA labeling expectations emphasize that device intended use and directions for use must align with device design and risk profile. Oral feeding syringes that are labeled "for oral feeding use only" and lack enteral connectivity, therefore are not consistent with FDA's definition of gastrointestinal tube accessories. These devices were classified with the higher device classification because an appropriate device category does not exist. Consistent with FDA's product classification framework, we propose the creation of a new FDA product code to accurately describe oral feeding syringes based on their intended use, design, and clinical function, distinct from enteral syringe accessories regulated under Product Code PNR. Establishing a separate product code would align with FDA's precedent of differentiating devices based on functional use and risk, while supporting clear labeling, appropriate standards application, and accurate device classification.
§ 878.4040, FXX, Surgical Apparel (mask)	Recommend exemption of surgical masks, subject to FDA recognized standards for safety and performance and design controls.	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices: Factor 1: A review of FDA's public databases shows a consistently low volume of reported adverse events, recalls, and complaint data for surgical masks. Reported issues are generally related to manufacturing

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		defects and not intrinsic device risks. Facemasks have decades of widespread, stable clinical use without systemic safety failures. Factor 2: Characteristics of the device necessary for its safe and effective performance are well established in long standing FDA-recognized consensus standards (e.g., ASTM F2100-23, ASTM F1862) and FDA guidance document on Surgical Masks. Factor 3: there is a low risk of device changes. The device failure modes are well established (e.g., earloop detachment, poor fit, thin material) and are readily detectable before commercial release. Furthermore, device changes are unlikely to cause patient/user harm, given the low-risk, non-invasive nature of facemasks. Factor 4: There is a low likelihood of technological evolution for surgical mask devices and any such change would not result in a change in the device's classification. Facemask technology is not rapidly evolving in ways that introduce new safety risks. No emerging innovations (coatings, filtration claims, antimicrobial agents) would push masks into higher risk categories. Manufacturers can manage innovation under existing regulations without reclassification.
§ 878.4040, FYA, Surgical apparel (surgical gown)	Recommend exemption of Level 3 Gowns subject to design controls and FDA-recognized consensus standards for safety and performance.	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices: Factor 1: Level 3 gowns have a long history of safe and effective use. Adverse events, recalls, and complaint data for Level 3 gowns are consistently low.

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		Factor 2: Performance and safety are well understood for these devices. There are well established standards for surgical gowns, including AAMI PB70 and ASTM F2407 which define barrier performance, construction, and labeling requirements. Devices follow established performance standards, meet claims, and comply with design specifications as outlined in the recognized consensus standards and FDA guidance document for "Surgical Gowns and Surgical Drapes". Factor 3: There is a low risk of device changes. The device failure modes are well established (e.g., seam defects, material tears, barrier failure) and are readily detectable before commercial release. Furthermore, device changes are unlikely to cause patient/user harm, given the low-risk, non-invasive nature of surgical gowns. Factor 4: There is a low likelihood of technological evolution for surgical gown devices and any such change would not result in a change in the device's classification. Surgical gowns are not rapidly evolving in ways that introduce new safety risks or push them into higher risk categories. Manufacturers can manage innovation under existing regulations without reclassification.
§ 878.4040, FYC Surgical apparel (isolation gown)	Recommend exemption of isolation gowns subject to design controls and FDA-recognized consensus standards for safety and performance.	These devices meet the 4 factors to determine that the device is appropriate for exemption for Class II devices: Factor 1: Isolation gowns have a long history of safe and effective use. Adverse events, recalls, and complaint data for Level 3 gowns are consistently low.

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REGULATION, PRODUCT CODE, DEVICE NAME	**PROPOSED PARTIAL LIMITATIONS**	**RATIONALE FOR PROPOSED CHANGE**
		Factor 2: Performance and safety are well understood for these devices. There are well established standards for surgical gowns which define barrier performance, construction, and labeling requirements. Devices follow established performance standards, meet claims, and comply with design specifications as outlined in the recognized consensus standards and FDA guidance document for "Surgical Gowns and Surgical Drapes". Factor 3: There is a low risk of device changes. The device failure modes are well established (e.g., seam defects, material tears, barrier failure) and are readily detectable before commercial release. Furthermore, device changes are unlikely to cause patient/user harm, given the low-risk, non-invasive nature of surgical gowns. Factor 4: There is a low likelihood of technological evolution for surgical gown devices and any such change would not result in a change in the device's classification. Surgical gowns are not rapidly evolving in ways that introduce new safety risks or push them into higher risk categories. Manufacturers can manage innovation under existing regulations without reclassification.

ADVAMED'S PROPOSED LIST OF CLASS I AND II IVDS FOR 510(K) EXEMPTION			
REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
§ 862.1035	CJW	Albumin concentration (serum and plasma). Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.	We offer multiple examples of routine nutritional and anemia-related immunochemistry and chemistry assays that we recommend for exemption from 510(k) requirements. These device types have well-established clinical applications and have been in widespread clinical use for decades. Their analytical performance characteristics are well characterized, standardized methods and reference materials are available, and performance issues are readily detected through routine laboratory quality control procedures and clinical correlation. Changes in device performance that could affect safety or effectiveness would either: • Be detected by users prior to patient harm through established laboratory controls, or • Not be expected to result in serious injury or life-threatening situations. Device malfunctions or user errors associated with these assays do not present a public health hazard and do not lead to a high degree of morbidity or mortality. These devices have no history of significant adverse events attributable to failures to meet performance specifications. FDA has extensive regulatory experience with these assays, and general controls are sufficient to provide reasonable assurance of safety and effectiveness.
Class I** § 862.1115	JJB	Urinary bilirubin and its conjugates (nonquantitative) test system Measurements of urinary bilirubin and its conjugates (nonquantitative) are used in the diagnosis and treatment of certain liver diseases.	FDA has exempted almost all Class I devices (with the exception of reserved devices) from the premarket notification requirement; 21 CFR 862.9(c)9 places near-patient tests on the reserved list, which means near-patient Class I devices continue to be subject to the 510(k) requirement. Under 510(1)(1), a Class I device is exempt from the premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. The automatic .9 limitation prevents low-risk Class I near-patient tests from being eligible for premarket notification (510(k) exemptions that apply to other tests, even when the device does not meet the statutory criteria under 510(1)(1). Almost three decades have passed since FDA first

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REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
			promulgated the limitation provisions in 1998, and during that time, state of technology, scientific knowledge have significantly evolved.
§ 862.1117	NBC	NT-proBNP (whole blood and plasma). Measurements of BNP are used as an aid in the diagnosis of patients with congestive heart failure.	Our proposed exemption applies only when the device is not intended for standalone diagnosis of acute myocardial infarction or other immediately life-threatening cardiac events, and when results are intended for monitoring, risk stratification, or adjunctive clinical assessment. These assays have well-established characteristics that are commonly used in non-acute clinical contexts. Errors are typically identified through clinical correlation and repeat testing. When limited to non-acute claims, device malfunctions would not be expected to result in serious injury or death.
§ 862.1140	JKR	Calcitonin test system (plasma and serum) Calcitonin measurements are used in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism (excessive activity of the parathyroid gland).	Calcitonin test systems have evolved from manual, less precise competitive assays to highly sensitive, automated sandwich-type immunoassays. This well-established technology is also largely used for patient monitoring. Further, we found no recalls or adverse events listed in the MAUDE database, indicating that the experience of these tests in the real-world setting is well performing.
Class I** § 862.1175	CHD, CHH, CGO	Cholesterol (total) test system (plasma and serum) Used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.	FDA has exempted almost all Class I devices (with the exception of reserved devices) from the premarket notification requirement; 21 CFR 862.9(c)9 places near-patient tests on the reserved list, which means near-patient Class I devices continue to be subject to the 510(k) requirement. Under 510(1)(1), a Class I device is exempt from the premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. The automatic .9 limitation prevents

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			low-risk Class I near-patient tests from being eligible for premarket notification (510(k) exemptions that apply to other tests, even when the device does not meet the statutory criteria under 510(1)(1). Almost three decades have passed since FDA first promulgated the limitation provisions in 1998, and during that time, state of technology, scientific knowledge have evolved.
Class I** § 862.1210	JLA, JLB	Creatine Test System (plasma, serum and urine) Measurements of creatine are used in the diagnosis and treatment of muscle diseases and endocrine disorders including hyperthyroidism.	FDA has exempted almost all Class I devices (with the exception of reserved devices) from the premarket notification requirement; 21 CFR 862.9(c)9 places near-patient tests on the reserved list, which means near-patient Class I devices continue to be subject to the 510(k) requirement. Under 510(1)(1), a Class I device is exempt from the premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. The automatic .9 limitation prevents low-risk Class I near-patient tests from being eligible for premarket notification (510(k) exemptions that apply to other tests, even when the device does not meet the statutory criteria under 510(1)(1). Almost three decades have passed since FDA first promulgated the limitation provisions in 1998, and during that time, state of technology, scientific knowledge have evolved.
§ 862.1235	MGS	Cyclosporine Used as an aid in the management of transplant patients receiving therapy with this drug.	We propose this exemption with a partial limitation. We would propose the exemption applies only to devices intended for routine therapeutic monitoring, excluding: Novel biomarkers New matrices New method principles not previously reviewed by FDA These assays are used for dose optimization and patient management, not for primary diagnosis. Their performance characteristics and clinical interpretation are well understood, and errors are detected through routine clinical and laboratory safeguards. When appropriately limited, exemption would not compromise patient safety and would reduce unnecessary regulatory burden.

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REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
§ 862.1295	CJN	Folate	We offer multiple examples of routine nutritional and anemia-related immunochemistry and chemistry assays that we recommend for exemption from 510(k) requirements. These device types have well-established clinical applications and have been in widespread clinical use for decades. Their analytical performance characteristics are well characterized, standardized methods and reference materials are available, and performance issues are readily detected through routine laboratory quality control procedures and clinical correlation. Changes in device performance that could affect safety or effectiveness would either: • Be detected by users prior to patient harm through established laboratory controls, or • Not be expected to result in serious injury or life-threatening situations. Device malfunctions or user errors associated with these assays do not present a public health hazard and do not lead to a high degree of morbidity or mortality. These devices have no history of significant adverse events attributable to failures to meet performance specifications. FDA has extensive regulatory experience with these assays, and general controls are sufficient to provide reasonable assurance of safety and effectiveness.
§ 862.1340	JIL	Urinary glucose (nonquantitative) test system. Used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia.	FDA has exempted almost all Class I devices (with the exception of reserved devices) from the premarket notification requirement; 21 CFR 862.9(c)9 places near-patient tests on the reserved list, which means near-patient Class I devices continue to be subject to the 510(k) requirement. Under 510(1)(1), a Class I device is exempt from the premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. The automatic .9 limitation prevents low-risk Class I near-patient tests from being eligible for premarket notification (510(k) exemptions that apply to other tests, even when the device does not meet the statutory criteria under 510(1)(1). Almost three decades have passed since FDA first

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REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
			promulgated the limitation provisions in 1998, and during that time, state of technology, scientific knowledge have evolved. The devices in this procode are waived by regulation for non-automated urinalysis (CLIA 42 CFR 493.15(c)(1)), which supports a presumption of low risk.
Class I** § 862.1435	JIN	Ketones (nonquantitative) test system A ketones (nonquantitative) test system is a device intended to identify ketones in urine and other body fluids. Identification of ketones is used in the diagnosis and treatment of acidosis (a condition characterized by abnormally high acidity of body fluids) or ketosis (a condition characterized by increased production of ketone bodies such as acetone) and for monitoring patients on ketogenic diets and patients with diabetes.	Waived by regulation for non-automated urinalysis (CLIA 42 CFR 493.15(c)(1)), which supports a presumption of low risk.
§ 862.1445	CEX	Lactate Dehydrogenase Isoenzyme (LDHi) (serum) Measurements of lactate dehydrogenase isoenzymes are used in the diagnosis and treatment of liver diseases, such as viral hepatitis, and myocardial infarction.	We propose a partial limitation: Exemption applies only when the device is not intended for standalone diagnosis of acute myocardial infarction or other immediately life-threatening cardiac events, and when results are intended for monitoring, risk stratification, or adjunctive clinical assessment. With this proposed limitation, these assays have well-established performance characteristics and are commonly used in non-acute clinical contexts. Errors are typically identified through clinical correlation and repeat testing. When limited to non-acute claims, device malfunctions would not be expected to result in serious injury

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REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
Class I** § 862.1450	KHP	Acid, Lactic, Enzymatic Method (whole blood, plasma) Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).	FDA has exempted almost all Class I devices (with the exception of reserved devices) from the premarket notification requirement; 21 CFR 862.9(c)9 places near-patient tests on the reserved list, which means near-patient Class I devices continue to be subject to the 510(k) requirement. Under 510(1)(1), a Class I device is exempt from the premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. The automatic .9 limitation prevents low-risk Class I near-patient tests from being eligible for premarket notification (510(k) exemptions that apply to other tests, even when the device does not meet the statutory criteria under 510(1)(1). Almost three decades have passed since FDA first promulgated the limitation provisions in 1998, and during that time, state of technology, scientific knowledge have significantly evolved.
Class I** § 862.1510	JMT	Nitrate (nonquantitative test system) (urine) Nitrite identification is used in the diagnosis and treatment of urinary tract infection of bacterial origin.	FDA has exempted almost all Class I devices (with the exception of reserved devices) from the premarket notification requirement; 21 CFR 862.9(c)9 places near-patient tests on the reserved list, which means near-patient Class I devices continue to be subject to the 510(k) requirement. Under 510(1)(1), a Class I device is exempt from the premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. The automatic .9 limitation prevents low-risk Class I near-patient tests from being eligible for premarket notification (510(k) exemptions that apply to other tests, even when the device does not meet the statutory criteria under 510(1)(1). Almost three decades have passed since FDA first promulgated the limitation provisions in 1998, and during that time, state of technology, scientific knowledge have significantly evolved.

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REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
Class I** § 862.1550	CEN	Urinary pH (nonquantitative test system) Estimations of pH are used to evaluate the acidity or alkalinity of urine as it relates to numerous renal and metabolic disorders and in the monitoring of patients with certain diets.	Waived by regulation for non-automated urinalysis (CLIA 42 CFR 493.15(c)(1)), which supports a presumption of low risk.
Class II (510(k) exempt)** § 862.1635	JGP CEK	Total Protein in Plasma or Serum Measurements obtained by this device are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders.	FDA has exempted these devices from premarket notification if intended for use in a centralized laboratory setting. However, 21 CFR 862.9(c)9 places near-patient tests on the reserved list, which means near-patient low-risk devices continue to be subject to the 510(k) requirement. Under 510(1)(1), a Class I device is exempt from the premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. In the case of a Class II device, the standard is that the device "no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness" (21 U.S.C. § 360(m). The automatic .9 limitation prevents low-risk near-patient tests from being eligible for premarket notification (510(k) exemptions that apply to other tests, even when the device does not meet the statutory criteria under 510(1)(1). Almost three decades have passed since FDA first promulgated the limitation provisions in 1998, and during that time, state of technology, scientific knowledge have evolved.
Class I** § 862.1645	JIQ, JIR	Urinary protein or albumin (nonquantitative) test system Urinary protein or albumin (nonquantitative) test system is a device intended to identify proteins or albumin in urine. Identification of urinary protein or albumin	Waived by regulation for non-automated urinalysis (CLIA 42 CFR 493.15(c)(1)), which supports a presumption of low risk.

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REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
		(nonquantitative) is used in the diagnosis and treatment of disease conditions such as renal or heart diseases or thyroid disorders, which are characterized by proteinuria or albuminuria.	
§ 862.1678	MLM	Tacrolimus (quantitative) Used as an aid in the management of transplant patients receiving therapy with this drug.	We propose a partial exemption. We would propose the exemption applies only to devices intended for routine therapeutic monitoring, excluding: Novel biomarkers New matrices New method principles not previously reviewed by FDA These assays are used for dose optimization and patient management, not for primary diagnosis. Their performance characteristics and clinical interpretation are well understood, and errors are detected through routine clinical and laboratory safeguards. When appropriately limited, exemption would not compromise patient safety and would reduce unnecessary regulatory burden.
Class I** § 862.1785	CDM	Urinary urobilinogen (nonquantitative test system) Estimations obtained by this device are used in the diagnosis and treatment of liver diseases and hemolytic (red cells) disorders.	Waived by regulation for non-automated urinalysis (CLIA 42 CFR 493.15(c)(1)), which supports a presumption of low risk.
§ 862.1810	CDD	Vitamin B12	We offer multiple examples of routine nutritional and anemia-related immunochemistry and chemistry assays that we recommend for exemption from 510(k) requirements. These device types have well-established clinical applications and have been in widespread clinical use for decades. Their analytical performance characteristics are well characterized, standardized methods and reference materials are available, and

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REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
			performance issues are readily detected through routine laboratory quality control procedures and clinical correlation. Changes in device performance that could affect safety or effectiveness would either: • Be detected by users prior to patient harm through established laboratory controls, or • Not be expected to result in serious injury or life-threatening situations. Device malfunctions or user errors associated with these assays do not present a public health hazard and do not lead to a high degree of morbidity or mortality. These devices have no history of significant adverse events attributable to failures to meet performance specifications. FDA has extensive regulatory experience with these assays, and general controls are sufficient to provide reasonable assurance of safety and effectiveness.
Class II** (510(k) exempt) § 862.2265	PFF	High throughput genomic sequence analyzer for clinical use: An analytical instrument system intended to generate, measure and sort signals in order to analyze nucleic acid sequences in a clinical sample. The device may include a signal reader unit; reagent handling, dedicated instrument control, and other hardware components; raw data storage mechanisms; data acquisition software; and software to process detected signals.	We propose removing the 862.9 limitation from Regulation 862.2265, as the instrument functions exclusively as a non-autonomous delivery and measurement platform with no independent clinical utility outside of its validated chemistry. Under the Product Code PFF regulatory framework, the system is already governed by stringent Special Controls that mandate the use of legally marketed reagents and validated software, rendering the "general purpose" 862.9 designation administratively redundant. Aligning with the FDA's "Least Burdensome" approach, our recommendation would ensure that safety and effectiveness are evaluated based on the unified diagnostic output—the patient result—rather than a hardware component. Specifically, our recommendation is supported by the following: • Integrated Functional Utility: The hardware, software, and assay form an inseparable "closed system" where the instrument lacks the capacity to generate meaningful clinical data in isolation. • Existing Special Controls: Product Code PFF already requires a rigorous, risk-based FDA submission for any new assay or significant workflow modification, providing comprehensive oversight without the need for additional limitations.

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REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
			• Mitigation of Redundancy: Since any expansion of the instrument's intended use triggers a mandatory submission, the 862.9 limitation offers no incremental safety benefit. Regulatory Alignment: Shifting to a unified workflow classification prevents the inconsistent regulation of a sub-component and focuses oversight on the system's true intended use
Class II** (Exempt, Special Controls, subject to limitations under .9) § 862.2570	NSU	Instrumentation for Clinical Multiplex Test Systems Intended to measure and sort multiple signals generated by an assay from a clinical sample. This instrumentation is used with a specific assay to measure multiple similar analytes that establish a single indicator to aid in diagnosis. Such instrumentation may be compatible with more than one specific assay. The device includes a signal reader unit, and may also integrate reagent handling, hybridization, washing, dedicated instrument control, and other hardware components as well as raw data storage mechanisms, data acquisition software, and software to process detected signals.	21 CFR 862.9(c)9 places near-patient tests on the reserved list, which means near-patient devices continue to be subject to 510(k). We propose that products under product code NSU are an example where the automatic requirement for 510(k) premarket notification is not clearly linked to any questions of risk that would arise, for example, due to differences in the indication (in this case, near-patient use), and that would therefore necessitate premarket notification. Notably, products under product code NSU not for near-patient use were previously exempted in 2019 (84 FR 71794) but information regarding such systems is still included in premarket notifications when part of a new assay/new instrument combination as per Section III of the guidance document "Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices." This guidance document also provides provisions for devices for point-of-care use (III B1) as well as guidance for risk-based assessments that manufacturers should consider when evaluating the applicability of the policy. In combination with the existing Special Controls for 862.2570, there are established and clear premarket expectations for such devices to manufacturers even in the absence of an automatic requirement for premarket notification. Removal of this automatic .9 limitation would resolve an administrative barrier while remaining consistent with current review processes and policies as covered by existing FDA guidance documents, thus streamlining review burden for FDA. Review of FDA postmarket databases also did not identify any specific POC-linked safety signals between 2021 and 2026. Specifically, between January 21, 2021 to March 6, 2026 (date of search), there have been five recalls for procode NSU, none of

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			which were for POC devices, suggesting that POC use does not inherently increase postmarket safety signals for products under NSU.4
§ 862.3320	KXT	Therapeutic Drug Monitoring Digoxin (serum and plasma) Measurements obtained by this device are used in the diagnosis and treatment of digoxin (cardiovascular drug) overdose and in monitoring levels of digoxin to ensure appropriate therapy.	We propose the following partial limitation: Exemption applies when devices are intended for quantitative monitoring in CLIA-certified moderate- or high-complexity laboratories, using established analytical methods and without novel detection technologies. These drug monitoring assays have been used for decades, with well-defined therapeutic ranges and established clinical monitoring practices. Potential errors are readily detected through serial monitoring, dose adjustment practices, and clinical signs and symptoms. FDA has extensive experience regulating these assays, and special controls and laboratory practices sufficiently mitigate risk.
§ 862.3350	DIP	Phenytoin Measurements obtained by this device are used in the diagnosis and treatment of overdose and in monitoring levels to ensure appropriate therapy.	We propose the following partial limitation: Exemption applies when devices are intended for quantitative monitoring in CLIA-certified moderate- or high-complexity laboratories, using established analytical methods and without novel detection technologies. These drug monitoring assays have been used for decades, with well-defined therapeutic ranges and established clinical monitoring practices. Potential errors are readily detected through serial monitoring, dose adjustment practices, and clinical signs and symptoms. FDA has extensive experience regulating these assays, and special controls and laboratory practices sufficiently mitigate risk.
§ 862.3560	JII	Lithium (serum and plasma) Measurements of lithium are used to assure that the proper drug dosage is administered in the treatment of	We propose the following partial limitation: Exemption applies when devices are intended for quantitative monitoring in CLIA-certified moderate- or high-complexity laboratories, using established analytical methods and without novel detection technologies.

[4] The MAUDE database was also reviewed and returned 54 MDRs between January 1, 2021, and March 6, 2026 (date of search). None were for POC devices although this may reflect lack of reporting as most IVD issues reported are related to assay problems; in addition, the POC use setting for these types of devices includes facilities and users who may not be aware of reporting requirements.

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REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
		patients with mental disturbances, such as manic-depressive illness (bipolar disorder).	These drug monitoring assays have been used for decades, with well-defined therapeutic ranges and established clinical monitoring practices. Potential errors are readily detected through serial monitoring, dose adjustment practices, and clinical signs and symptoms. FDA has extensive experience regulating these assays, and special controls and laboratory practices sufficiently mitigate risk.
§ 862.3645	LEG, KLT	Valproic Acid, Carbamazepine (serum and plasma) Measurements obtained by this device are used to aid in determining whether a patient is taking the prescribed dosage level of these drugs.	We propose the following partial limitation: Exemption applies when devices are intended for quantitative monitoring in CLIA-certified moderate- or high-complexity laboratories, using established analytical methods and without novel detection technologies. These drug monitoring assays have been used for decades, with well-defined therapeutic ranges and established clinical monitoring practices. Potential errors are readily detected through serial monitoring, dose adjustment practices, and clinical signs and symptoms. FDA has extensive experience regulating these assays, and special controls and laboratory practices sufficiently mitigate risk.
§ 862.3660	DLZ	Phenobarbital Measurements obtained by this device are used in the diagnosis and treatment of phenobarbital use or overdose and in monitoring levels of phenobarbital to ensure appropriate therapy.	We propose the following partial limitation: Exemption applies when devices are intended for quantitative monitoring in CLIA-certified moderate- or high-complexity laboratories, using established analytical methods and without novel detection technologies. These drug monitoring assays have been used for decades, with well-defined therapeutic ranges and established clinical monitoring practices. Potential errors are readily detected through serial monitoring, dose adjustment practices, and clinical signs and symptoms. FDA has extensive experience regulating these assays, and special controls and laboratory practices sufficiently mitigate risk.
§ 862.3840	OUF, OAV	Everolimus, Mycophenolic Acid (whole blood) Measurements are used as an aid in management of transplant patients receiving therapy with sirolimus.	We propose a partial exemption. We would propose the exemption applies only to devices intended for routine therapeutic monitoring, excluding: Novel biomarkers New matrices New method principles not previously reviewed by FDA

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			These assays are used for dose optimization and patient management, not for primary diagnosis. Their performance characteristics and clinical interpretation are well understood, and errors are detected through routine clinical and laboratory safeguards. When appropriately limited, exemption would not compromise patient safety and would reduce unnecessary regulatory burden.
§ 862.3880	LGS	Theophylline (serum and plasma) Measurements obtained by this device are used in the diagnosis and treatment of theophylline overdose or in monitoring levels of theophylline to ensure appropriate therapy.	We propose the following partial limitation: Exemption applies when devices are intended for quantitative monitoring in CLIA-certified moderate- or high-complexity laboratories, using established analytical methods and without novel detection technologies. These drug monitoring assays have been used for decades, with well-defined therapeutic ranges and established clinical monitoring practices. Potential errors are readily detected through serial monitoring, dose adjustment practices, and clinical signs and symptoms. FDA has extensive experience regulating these assays, and special controls and laboratory practices sufficiently mitigate risk.
§ 862.3950	LEH	Vancomycin (serum) Measurements obtained by this device are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.	We propose the following partial limitation: Exemption applies when devices are intended for quantitative monitoring in CLIA-certified moderate- or high-complexity laboratories, using established analytical methods and without novel detection technologies. These drug monitoring assays have been used for decades, with well-defined therapeutic ranges and established clinical monitoring practices. Potential errors are readily detected through serial monitoring, dose adjustment practices, and clinical signs and symptoms. FDA has extensive experience regulating these assays, and special controls and laboratory practices sufficiently mitigate risk.
§ 864.3700	PSY PZZ QKQ	Whole Slide Imaging System An automated digital slide creation, viewing, and management system intended as an aid to the pathologist to review and interpret digital images of surgical pathology slides. The system generates digital images that	We believe these devices meet the criteria from the statute and the Federal Register notice.

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		would otherwise be appropriate for manual visualization by conventional light microscopy.	
§ 864.5250	OYE GKZ PMG LIZ	Flow cytometric reagents and accessories Counter, differential cell Automated multicolor fluorescent imaging cytometric analysis system Assay, t lymphocyte surface marker Assay, b lymphocyte marker	The characteristics of the devices necessary for their safe and effective performance are well established by the requirements in special controls "Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells." The risk mitigations of the special controls' guidance concerning design verification and validation can be achieved to provide equivalent assurance of safety and effectiveness and documented in the design history file (DHF) rather than providing that information to the FDA under section 510(k). The history of devices being cleared under this regulation for substantial equivalence since 1977 also indicates that characteristics of safety and effectiveness are well established. Additionally, the clinical application of the devices, including test results in the case of an IVD, are well established. Changes in the devices that could affect safety and effectiveness will be readily detectable by users through routine Quality Control (QC) testing as specified under the controls requirements in the special controls guidance in this regulation. Any changes to the device would not likely result in a change in the device's classification (Class II) since most instrument changes are related to improvements of the existing technology and reagent changes would be subject to the existing indications restricted in the limitations of exemption in 21CFR864.9. MAUDE search results for the listed product codes with a filter for Product Problem "false claim" from 01JAN1991 to 26FEB2026 show that the devices do not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the devices.

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REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
§ 864.5400	KQG GKP GKN PBA	Coagulation Instrument An automated or semiautomated device used to determine the onset of clot formation for *in vitro* coagulation studies.	We appreciated FDA's prior exemption. In addition, we would propose including PBA, KQG, GKP, and GKN, which continue to be subject to the 510(k) requirement. We have identified these as appropriate for inclusion and comprehensive of the regulation subject to 510(k) exemption. These product codes are well-established technologies that are not in widespread use and are subject to special controls.
§ 864.5425	JPA	Multipurpose System for *In Vitro* Coagulation Studies A multipurpose system for *in vitro* coagulation studies is a device consisting of one automated or semiautomated instrument and its associated reagents and controls. The system is used to perform a series of coagulation studies and coagulation factor assays.	We appreciated FDA's exemption of control reagents. In addition to control reagents, we request FDA exempt JPA (analyzer), which is consistent with exemption of other analyzers.
Class I** § 864.7675	LJX	Leukocyte peroxidase test	Waived by regulation for non-automated urinalysis (CLIA 42 CFR 493.15(c)(1)), which supports a presumption of low risk.
§ 866.2900	JTW	Microbiological specimen collection and transport device A specimen collecting chamber intended for medical purposes to preserve the viability or integrity of microorganisms in specimens during storage of specimens after their collection and during their transport from the collecting area to the laboratory. The device may be labeled or otherwise represented as sterile. The device aids in the diagnosis of	C&S urine tube Products under JTW are Class I, but still require a 510(k), which is inconsistent with most other product codes related to urine microbiology that are Class I, but 510(k) exempt (e.g. JXA). As such we recommend making the JTW product code Class I exempt to be consistent with other similar products in the space.

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REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
		disease caused by pathogenic microorganisms.	
§ 866.3170	OBF	Nucleic acid-based hepatitis C virus ribonucleic acid tests (serum and plasma) Intended for prescription use as an aid in the diagnosis of HCV infection in specified populations, and/or as an aid in the management of HCV-infected patients including guiding the selection of genotype-specific treatment in individuals with chronic HCV infection. Not intended for use as a donor screening test for the presence of HCV antibodies in blood, blood products, or tissue donors.	Nucleic acid tests (NATs) for Hepatitis C Virus (HCV) have transitioned from labor-intensive manual procedures with limited range to high-speed, fully automated systems capable of ultra-sensitive detection. Testing has moved from a "two-step" laboratory process that could take 3.5 to 7 days to "sample-to-answer" automation.
Class II § 866.3332	NXD	Reagents for detection of specific novel influenza A viruses. intended for use in a nucleic acid amplification test to directly detect specific virus RNA in human respiratory specimens or viral cultures. Detection of specific virus RNA aids in the diagnosis of influenza caused by specific novel influenza A viruses in patients with clinical risk of infection with these viruses, and also aids in the presumptive laboratory identification of specific novel influenza A viruses to provide epidemiological	Reagents for detecting novel influenza A viruses have transformed from labor-intensive, generic components into highly specific, molecularly engineered tools that enable rapid subtyping and pandemic monitoring. Modern reagents, such as nanoparticle-labeled antibodies and europium-based immunoassays, have increased sensitivity to allow for detection even at low viral loads. The shift from traditional polyclonal antibodies to monoclonal antibodies and aptamers (synthetic DNA/RNA ligands) has significantly reduced cross-reactivity and improved the limit of detection (LOD). Finally, they have shifted from mostly manual extraction to a fully automated "simple to answer" test.

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REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
		information on influenza. These reagents include primers, probes, and specific influenza A virus controls.	
§ 866.3780	GMN, GLZ, GMM, LJK, LGD, LLA	Toxoplasma gondii serological reagents (serum) Aids in diagnosis of toxoplasmosis caused by the parasitic protozoan Toxoplasma gondii and provides epidemiological information on this disease. Congenital toxoplasmosis is characterized by lesions of the central nervous system, which if undetected and untreated may lead to brain defects, blindness, and death of an unborn fetus. The disease is characterized in children by inflammation of the brain and spinal cord.	Toxoplasma gondii serological reagents have shifted from crude, cell-culture-derived lysates to highly defined recombinant and chimeric proteins, drastically improving the accuracy of timing infections during pregnancy. These tests in the '90s were manual and highly variable but they are now fully automated and standardized. In particular, the POC tests had limited accuracy but now have high accuracy lateral flow. Further, the lack of recalls in the MAUDE database indicate that these tests perform well in the real-world setting.
§ 866.3980	OCC	Respiratory viral panel multiplex nucleic acid assay (qualitative) Intended to simultaneously detect and identify multiple viral nucleic acids extracted from human respiratory specimens or viral culture. The detection and identification of a specific viral nucleic acid from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection when used in	Respiratory Viral Panel (RVP) multiplex assays have evolved from specialized, research-only tools to the clinical "gold standard" for syndromic diagnosis. The primary shifts have been from manual, time-consuming culture and antigen tests to fully automated, high-plex molecular systems.

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		conjunction with other clinical and laboratory findings. The device is intended for detection and identification of a combination of the following viruses: (1) Influenza A and Influenza B; (2) Influenza A subtype H1 and Influenza A subtype H3; (3) Respiratory Syncytial Virus subtype A and Respiratory Syncytial Virus subtype B; (4) Parainfluenza 1, Parainfluenza 2, and Parainfluenza 3 virus; (5) Human Metapneumovirus; (6) Rhinovirus; and (7) Adenovirus.	
§ 866.3981	QOF	Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test. Intended to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test is an *in vitro* diagnostic device intended for the	The lack of recalls in the MAUDE database indicate that these tests perform well in the real-world setting.

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REGULATION	**PRODUCT CODE**	**NAME/INDICATIONS FOR USE**	**RATIONALE FOR EXEMPTION**
		detection and identification of SARS-CoV-2 and other microbial agents when in a multi-target test in human clinical respiratory specimens from patients suspected of respiratory infection who are at risk for exposure or who may have been exposed to these agents. The device is intended to aid in the diagnosis of respiratory infection in conjunction with other clinical, epidemiologic, and laboratory data or other risk factors.	
§ 866.4001	PZF	A multiplex respiratory panel to detect and identify emerging respiratory pathogen(s) and common respiratory pathogens in human clinical specimens.	Multiplex respiratory panels have shifted from being niche research tools to fully automated, "sample-to-answer" syndromic tests that can identify over 20 pathogens in an hour. The most significant leap has been the ability to integrate novel/emerging pathogens (like MERS-CoV or SARS-CoV-2) into standard clinical workflows without sacrificing the speed or accuracy of testing for common viruses. Testing has moved from "open-platform" PCR that took 8–24 hours of manual labor to closed-cartridge systems. These provide results in 45–75 minutes with less than 2 minutes of hands-on time. Manufacturers can now rapidly update reagent "menus" to include new variants. For example, during the 2009 H1N1 and 2020 COVID-19 outbreaks, multiplex panels were updated within months to include specific primers for novel strains alongside seasonal ones. High-performance multiplexing has moved out of central labs and into ERs and urgent care centers. This allows for immediate "test-and-treat" or "test-and-isolate" decisions, reducing hospital admission times by up to 24 hours. Further, the lack of recalls in the MAUDE database indicate that these tests perform well in the real-world setting.

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§ 866.5240	CZW, DBI	Complement C3; Complement C4 (serum) Complement is a group of serum proteins which destroy infectious agents. Measurements of these proteins aids in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.	These assays are used primarily for monitoring, risk assessment, and disease management, rather than for standalone diagnosis of acute or life-threatening conditions. The clinical significance of results is well understood, and erroneous results are generally identified through repeat testing, trend analysis, or clinical context. Analytical methodologies are mature and standardized, and these device types conform to applicable FDA special controls and guidance. Errors or malfunctions would not be expected to result in serious injury or death, supporting exemption from premarket notification requirements.
§ 866.5270	DCK	C-Reactive Protein (CRP), Wide Range CRP (serum, other bodily fluids) Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.	These assays are used primarily for monitoring, risk assessment, and disease management, rather than for standalone diagnosis of acute or life-threatening conditions. The clinical significance of results is well understood, and erroneous results are generally identified through repeat testing, trend analysis, or clinical context. Analytical methodologies are mature and standardized, and these device types conform to applicable FDA special controls and guidance. Errors or malfunctions would not be expected to result in serious injury or death, supporting exemption from premarket notification requirements.
§ 866.5340	DBF	Ferritin	We offer multiple examples of routine nutritional and anemia-related immunochemistry and chemistry assays that we recommend for exemption from 510(k) requirements. These device types have well-established clinical applications and have been in widespread clinical use for decades. Their analytical performance characteristics are well characterized, standardized methods and reference materials are available, and performance issues are readily detected through routine laboratory quality control procedures and clinical correlation. Changes in device performance that could affect safety or effectiveness would either:

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			• Be detected by users prior to patient harm through established laboratory controls, or • Not be expected to result in serious injury or life-threatening situations. Device malfunctions or user errors associated with these assays do not present a public health hazard and do not lead to a high degree of morbidity or mortality. These devices have no history of significant adverse events attributable to failures to meet performance specifications. FDA has extensive regulatory experience with these assays, and general controls are sufficient to provide reasonable assurance of safety and effectiveness.
§ 866.5510	CZP	Immunoglobulin A (IgA), G (IgG), and M (IgM) (serum) Measurement of these immunoglobulins aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.	These assays are used primarily for monitoring, risk assessment, and disease management, rather than for standalone diagnosis of acute or life-threatening conditions. The clinical significance of results is well understood, and erroneous results are generally identified through repeat testing, trend analysis, or clinical context. Analytical methodologies are mature and standardized, and these device types conform to applicable FDA special controls and guidance. Errors or malfunctions would not be expected to result in serious injury or death, supporting exemption from premarket notification requirements.
§ 866.5600	DFC	Lipoprotein(a)	These assays are well-established tools for long-term cardiovascular risk assessment and patient monitoring. They are not intended as the sole basis for diagnostic decision-making. Performance characteristics are well understood, reference methods are available, and results are interpreted in conjunction with other clinical information. Laboratory quality systems readily detect analytical errors, and device failures would not be expected to pose a public health risk. FDA's extensive experience with lipid testing supports exemption under general controls.

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§ 866.5680	DDR	Myoglobin	We propose an exemption with a partial limitation: Exemption applies only when the device is not intended for standalone diagnosis of acute myocardial infarction or other immediately life-threatening cardiac events, and when results are intended for monitoring, risk stratification, or adjunctive clinical assessment. When so limited, these assays have well-established performance characteristics and are commonly used in non-acute clinical contexts. Errors are typically identified through clinical correlation and repeat testing. When limited to non-acute claims, device malfunctions would not be expected to result in serious injury
§ 866.5775	DHR	Rheumatoid Factor (RF)	These assays are used primarily for monitoring, risk assessment, and disease management, rather than for standalone diagnosis of acute or life-threatening conditions. The clinical significance of results is well understood, and erroneous results are generally identified through repeat testing, trend analysis, or clinical context. Analytical methodologies are mature and standardized, and these device types conform to applicable FDA special controls and guidance. Errors or malfunctions would not be expected to result in serious injury or death, supporting exemption from premarket notification requirements.
Class II § 866.5880	DDG	Transferrin	We offer multiple examples of routine nutritional and anemia-related immunochemistry and chemistry assays that we recommend for exemption from 510(k) requirements. These device types have well-established clinical applications and have been in widespread clinical use for decades. Their analytical performance characteristics are well characterized, standardized methods and reference materials are available, and performance issues are readily detected through routine laboratory quality control procedures and clinical correlation. Changes in device performance that could affect safety or effectiveness would either: • Be detected by users prior to patient harm through established laboratory controls, or • Not be expected to result in serious injury or life-threatening situations.

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			Device malfunctions or user errors associated with these assays do not present a public health hazard and do not lead to a high degree of morbidity or mortality. These devices have no history of significant adverse events attributable to failures to meet performance specifications. FDA has extensive regulatory experience with these assays, and general controls are sufficient to provide reasonable assurance of safety and effectiveness.
(Special Controls) § 866.5950	PTA	Genetic health risk assessment system	Direct To Consumer (DTC) Genetic Health Risk (GHR) tests are already partially exempted per Federal Register 82 FR 51633, provided they meet specific requirements that are described in the regulation for this type of test and are not for specific higher risk uses. We therefore propose that, in the spirit of efficient use of FDA premarket review resources to promote innovation while protecting patients and public health, FDA consider fully exempting DTC GHR tests. DTC GHR tests are not intended to be the sole basis of any type of medical decision making, as by definition they are devices intended only to inform users of lifestyle choices and/or encourage conversations with healthcare professionals. FDA's existing regulatory framework for DTC Genetic Health Risk (GHR) tests demonstrates that, when risk is appropriately mitigated through special controls and limitations on intended use, the Agency does not require premarket review for subsequent product claim expansions. With such partial exemption already in place, it appears that the overall risk to health from failing to meet performance specifications is already so low that initial Agency premarket review primarily focuses on mitigating against misbranding (e.g. correct labeling, communication of risks) rather than safety risks associated with adulteration (e.g. due to poor performance). In cases where identified health risks are primarily associated with labeling or user comprehension, premarket submission reviews add limited public-health value

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			especially as FDA has already undertaken public health education efforts to inform consumers of the risks associated with these tests. Enforcement against misbranding (and adulteration) are among established Agency authorities and Controls, and FDA has already exercised such actions in cases of more significant public health concern, such as 2019 actions against manufacturers of DTC pharmacogenetic tests. Since 2017, no recalls have been reported for product code PTA. Rather, review of the MAUDE database shows a single report for product code PTA, where no adverse event was reported but the reporter (a healthcare professional) complains about the validity of results. This suggests that the healthcare industry is aware of the limitations of DTC GHR tests, including limitations with the clinical actionability of results. FDA postmarket enforcement and continued education of the public may provide more scalable approaches to public health risk management and FDA oversight of such tests, rather than continued FDA premarket review, of such tests.
(Special Controls) § 866.6000	QNC	Whole exome sequencing constituent device	Consistent with the rationale outlined above for devices under Product Code PFF, we propose exemption from premarket review for products under Product Code QNC (21 CFR 866.6000). Devices in this regulation are, by definition, constituent devices intended as inputs to downstream test systems and therefore do not function as standalone test systems. FDA has historically proposed novel approaches to NGS regulation; for example, proposing use of consensus standards or recommending that test developers (including clinical laboratories) develop technical metrics for qualifying components in manufacturing of NGS workflows. The 2018 FDA NGS Guidance Document also indicates FDA's intent to consider exempting such tests from premarket review altogether. Considerations for exempting such NGS-based tests in the 2018 guidance document highlight the need for innovative approaches and methods for assuring valid analytical, scientific, and clinical evidence that could take the place of premarket review.

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			With the development of new standards (e.g., ISO 5649:2024, intended for medical/clinical laboratories) and guidelines(e.g., CLSI EP49, not yet recognized as an FDA consensus standard, but includes several FDA authors) intended to support scientific, analytical and clinical validity for manufacturers and clinical laboratories who are the primary developers of NGS-based tests, we propose that FDA can now consider exempting certain low-risk NGS-associated devices. Specifically, we propose the following for FDA's consideration with respect to products under QNC: Intended Use as a Constituent Device: Under 21 CFR 866.6000, constituent devices cannot operate autonomously and do not generate clinically meaningful results on their own. As reflected in the generic device description, such devices must be used with downstream germline DNA test systems that hold FDA marketing authorization to impact clinical decision making. Their intended use is inherently limited to a complementary or supporting functionality within a complete test system. Existing Special Controls and ISO 13485/QMSR: Product Code QNC includes robust special controls addressing intended use, labeling, design verification/validation, and modification controls. With the incorporation of ISO 13485 by reference into the QMSR, manufacturers face strengthened, risk-based expectations for: • supplier qualification and monitoring (ISO 13485:2016 §7.4), • alignment of supplier controls with product risk, and • ongoing lifecycle oversight of constituent components. For example, the special controls for 866.6000 require that any changes to associated bioinformatics software be communicated to downstream developers, and that the constituent device manufacturer maintain a defined communication plan. Under QMSR, downstream developers must maintain ongoing oversight of these changes as part of their supplier control program.

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			With these strengthened QMSR obligations in place, an additional FDA review step for the constituent device alone creates an unnecessary regulatory review barrier without adding meaningful health risk mitigation. Exemption could support a more coherent, streamlined TPLC regulatory pathway with QMSR and supplier qualification requirements taking the place of FDA oversight. Furthermore, modern regulatory approaches such as PCCP now enable additional FDA oversight of manufacturer change processes for downstream tests. FDA now has new and innovative regulatory options to mitigate any remaining risks following exemption of system components. Regulatory Alignment: Exempting constituent devices under 21 CFR 866.6000 from standalone premarket review aligns regulatory oversight with the actual risk posed by these products. This unified, risk-proportionate approach reduces inconsistent regulation of constituent devices and supports FDA's broader efforts to modernize and harmonize device oversight. As of 2026, no product recalls have been reported for product code QNC and no MDRs have been filed in MAUDE since 2020, indicating a stable postmarket safety profile and no observed failures to meet performance specifications. While MAUDE reporting has inherent limitations, this multi-year absence of adverse trends suggests that existing general and special controls, combined with strengthened risk-based requirements under QMSR and ISO 13485, could effectively ensure safety and performance. Downstream FDA-authorized test systems remain fully responsible for verifying and validating analytical and clinical performance. As such, exemption of constituent devices under 866.6000 would not be expected to adversely impact public health. Exemption of constituent devices under 21 CFR 866.6000 would not reduce the Agency's overall oversight of clinically meaningful changes but would rather streamline it by focusing on complete test systems where clinical performance and patient risk reside.

Single Asterisk Indicates Enforcement Discretion*
*Double Asterisk** Indicates Class I 510(k) Exempt and Should be Exempt Even if Intended for POC Setting*