701 Pennsylvania Avenue, Ste. 800
Washington, DC 20004–2654
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

September 30, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-D-0967 ***"Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements; Draft Guidance for Industry and Food and Drug Administration Staff."***

Dear Sir or Madam:

The Advanced Medical Technology Association ("AdvaMed") is pleased to provide comments on FDA's draft guidance "*Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements; Draft Guidance for Industry and Food and Drug Administration Staff."*

AdvaMed represents manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatment. Our members range from the smallest to the largest medical technology innovators.

AdvaMed commends the Agency for proposing a substantial number of low-risk devices for which a 510(k) submission is no longer required. We believe, however, that there are many other low-risk, well-known and understood devices that also should be exempted from premarket notification. We have provided our recommendations for these additional devices (both Class I "Reserved" and Class II devices), along with our rationale for exempting them from premarket notification requirements in the attached.

Thank you for the opportunity to submit comments on this draft guidance document.

Respectfully submitted,

/s/

Sharon A. Segal, Ph.D.
Vice President
Technology and Regulatory Affairs
Attachments

ATTACHMENT

Additional Class I Devices Proposed for 510(k) Exemption

Regulation	Product Code	Name	Rationale for Exemption
CLINICAL CHEMISTRY AND TOXICOLOGY DEVICES[i,ii]			
862.1680	CDZ	Radioimmunoassay (Testosterones and Dihydrotestosterone)	The rationale for IVDs presented in this table is provided in Endnote #1
862.1065	JIG	Ammonia test system	
	JIF		
	JIE		
	JID		
862.1410	JIZ	Iron (non-heme) test system	
	CFM		
	JIY		
	JJA		
862.1580	CEO	Phosphorous (inorganic) test system	
862.3240	DLI	Cholinesterase test system	
	DIG		
	DIH		
	DOH		
	DMR		
862.3750	DIK	Thin Layer Chromatography for Quinine Analysis	
	LAL	EAS Chromatography for Quinine	
	LAM	High Pressure Liquid Chromatography for Quinine	
864.7040	KHF	Adenosine triphosphate release assay	
	JWR		

Regulation	Product Code	Name	Rationale for Exemption
MICROBIOLOGY AND IMMUNOLOGY DEVICES[1]			
866.3110	GSP	Antiserum, Fluorescent, Campylobacter Fetus	The rationale for IVDs presented in this table is provided in Endnote #1
	LQO	DNA-Reagents, Campylobacter Spp.	
	LQP	Campylobacter Spp.	
	LYR	Campylobacter Pylori	
	MSQ	Urea Test (Breath or Blood)	
866.3235	GNP	Epstein-Barr Virus CF Antiserum	
	GNQ	Epstein-Barr Virus CF Antigen (Including CF Control)	
	JRY	Fluorescent Antiserum for Epstein-Barr Virus Assay	
	LJN	Epstein-Barr Virus IF IgM Antibody	
	LLM	Epstein-Barr Virus Nuclear Antigen Test	
	LSE	Epstein-Barr Virus, Other	
	LSF	Epstein-Barr Virus DNA-Reagents,	
	MCD	EBV Capsid Antigen	
866.3870	GNF	Trypanosoma spp. serological reagents	
	GND		
	GNE		
	MIU		
	MIV		
	OUZ		
	LOO		

Regulation	Product Code	Name	Rationale for Exemption
DENTAL DEVICES			
872.4200	EBW EFB NYL EFA EGS EKX EKY	Dental handpiece and accessories	Exempt subject to general controls. Currently, Class I devices that are used with a dental handpiece are exemption (e.g., intraoral dental drill (21 C.F.R. § 872.4130), dental diamond instruments (21 C.F.R. § 872.4535), and fiber optic dental lights (21 C.F.R. § 872.4620)). Dental handpieces do not meet FDA's reserved criteria.[iii]
872.6250	KLC NRU	Dental chair and accessories	Exempt subject to general controls. Only dental chairs with a dental operative unit are currently reserved.
872.6640	EHZ PFX DYN EIA NRD EBR	Dental operative unit and accessories	Exempt subject to general controls. Currently, accessories under this classification that contact the patient are exempt. None meet FDA's reserved criteria.
872.6710	ECG	Boiling water sanitizer	Exempt subject to general controls. This is a basic AC-powered heating unit that brings water to 100° C.
GENERAL HOSPITAL AND PERSONAL USE DEVICES			
880.5090	KMF	Liquid bandage	Exempt subject to general controls. The intended use is to cover and protect the skin. Current exemption applies to topical skin protectant, but does not apply to indications for covering and protecting wounds and burns. None meet FDA's reserved criteria.
880.5680	FRP OUW	Pediatric position holder	Exempt subject to general controls. Device type does not meet reserved criteria. Note: Currently exempt from GMPs.
882.1420	GWF	Electroenceophalogram (EEG) signal spectrum analyzer	Exempt subject to general controls. Note: There are only 18 clearances since 1976 for this product code, and only 2 in the last 15 years.
882.4060	HCD	Ventricular cannula	Exempt subject to general controls. Note: Only ventricular cannulae made from stainless steel are currently exempt. Material issues are not a justification for invoking the reserved criteria. Similar cannulae for general surgical use already are exempt and are used in neurology. Also, there are only 2 510(k) clearances under product code "HCD" since 1976.

Regulation	Product Code	Name	Rationale for Exemption
882.4545	GWK	Shunt system implantation instrument	Exempt subject to general controls. Note: Only instruments made from stainless steel are currently exempt. Material issues are not a justification for invoking the reserved criteria. Manual surgical instruments for general surgery and all other medical specialties already are exempt and are used in neurology. Note: There is only 510(k) clearance under product code "GYK" since 1976.
PHYSICAL MEDICINE DEVICES			
890.3850	LBE IOR	Mechanical wheelchair	Exempt subject to general controls. Reserved criteria are not met. Wheelchairs do not prevent impairment of human health and they do not represent a potential for unreasonable risk of illness or injury. Note: Accessories (21 C.F.R. § 880.3910) and components (21 C.F.R. 880.3920) to wheelchairs are currently exempt.
890.5710	OMW IMD MPO	Hot or cold disposable packs	Exempt subject to general controls. Meets reserved criteria if indicated for use on infants. Note: Water circulating hot packs (21 C.F.R. § 890.5720), moist heat packs (21 C.F.R. § 890.5730), and powered heating pads (Class II, 21 C.F.R. § 890.5740) are exempt with no limitations regarding use on infants.

Additional Class II Devices Proposed for 510(k) Exemption

Regulation	Product Code	Name	Rationale for Exemption
CLINICAL CHEMISTRY AND TOXICOLOGY DEVICES			
862.1035	CJZ	Hydroxyazobenzene-benzoic acid	The rationale for IVDs presented in this table is provided in Endnote #1.
	CIX	Bromcresol green dye-binding	
	CJW	Bromcresol purple dye-binding	
	CJQ	Radial immunodiffusion	
	CJG	Tetrabromo-m-cresolsulfonphthalein	
	CJF	Tetrabromophenolphthalein	
862.1050	CJO	Alpha-naphthyl phosphate	
	CJL	Beta glycerophosphate	
	CJI	Disodium phenylphosphate	
	CIN	Electrophoretic separation	
	CJE	Nitrophenylphosphate	
862.1050	CJK	Phenolphthalein phosphate	
	CKF	Phenylphosphate	

Regulation	Product Code	Name	Rationale for Exemption
	NEO	Alkaline phosphatase or isoenzymes test system	The rationale for IVDs presented in this table is provided in Endnote #1.
	CJH	Thymol blue monophosphate	
	CIO	Thymolphthalein monophosphate	
862.1070	CJA	Amylase test system	
	JFJ	Amylase, catalytic methods	
	KHM	Amylase, Nephelometric	
	CJD	Amylase, Nitrosalicylate reduction	
	CIK	Amylase, Radial diffusion	
	CIJ	Amylase, Saccharogenic	
	CIW	Amylase, Starch-dye bound polymer	
862.1695	CEC	Free thyroxine test system	
862.3100	DIT	Thin Layer Chromatography Method for Amphetamine	
	DJL	Free Radical Assay for Amphetamine	

Regulation	Product Code	Name	Rationale for Exemption
	DJP	Radioimmunoassay for Amphetamine	The rationale for IVDs presented in this table is provided in Endnote #1.
	DKZ	Enzyme Immunoassay for Amphetamine	
	DNI	Liquid Chromatography for Amphetamine	
	DOD	Gas Chromatography for Amphetamine	
	DPJ	RIA for Amphetamine (125-I); Goat Antibody, Ammon. Sulfate Separation	
	LCM	Phencyclidine enzyme immunoassay	
862.3250	DIN	Gas Chromatography Method for Cocaine	
	DIO	Enzyme Immunoassay for Cocaine and Cocaine Metabolites	
862.3250	DIR	Free Radical Assay for Cocaine	
	DLN	Hemagglutination Method for Cocaine Metabolites (Benzoylecgnonine)	
	DMN	Thin Layer Chromatography Method for Cocaine	

Regulation	Product Code	Name	Rationale for Exemption
	DNG	Free Radical Test Method for Benzoylecgnonine	The rationale for IVDs presented in this table is provided in Endnote #1.
	DOM	Thin Layer Chromatography for Benzoylecgnonine	
	JXO	Enzyme Immunoassay for Cocaine	
	KLN	Radioimmunoassay for Cocaine Metabolite	
	LAC	High Pressure Liquid Chromatography for Cocaine and Cocaine Metabolites	
862.3610	DJC	Thin Layer Chromatography Method for Metamphetamine	The rationale for IVDs presented in this table is provided in Endnote #1.
	LAF	Gas Chromatography Method for Methamphetamine	
	LAG	High Pressure Liquid Chromatography Method for Methamphetamine	
862.3870	DKE	Tetrahydrocannabinol Test Reagents	
	LAT	Cannabinoid(s) Radioimmunoassay	

Regulation	Product Code	Name	Rationale for Exemption
	LDJ	Cannabinoids Enzyme Immunoassay	
MICROBIOLOGY AND IMMUNOLOGY DEVICES[1]			
866.5100	DHN	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control	The rationale for IVDs presented in this table is provided in Endnote #1.
	KTL	Anti-DNA Indirect Immunofluorescent Solid Phase	
866.5100	LJM	Antinuclear Antibody (Enzyme-Labeled), Antigen, Controls	
	LKJ	Antinuclear Antibody, Antigen, Control	
	LKO	Anti-RNP Antibody, Antigen and Control	
	LKP	Anti-SM Antibody, Antigen and Control	
	LLL	Extractable Antinuclear Antibody, Antigen and Control	The rationale for IVDs presented in this table is provided in Endnote #1.
	LRM	Anti-DNA Antibody (Enzyme-Labeled), Antigen, Control	
	LSW	Anti-DNA Antibody, Antigen and Control	

Regulation	Product Code	Name	Rationale for Exemption
	MQA	Anti-Ribosomal P Antibodies	
	NYO	AutoAntibodies, Anti-Ribonucleic Acid Polymerase (RNAP) III Antibody	
	OBE	Anti-SS-A 52 AutoAntibodies	
866.5130	OBZ	Alpha-1-Antitrypsin kit, qualitative phenotype	The rationale for IVDs presented in this table is provided in Endnote #1.
	DEM	Alpha-1-Antitrypsin, Antigen, Antiserum, control	
	DEI	Alpha-1-Antitrypsin, fitc, Antigen, Antiserum, control	
	DFB	Alpha-1-Antitrypsin, rhodamine, Antigen, Antiserum, control	
866.5660	MOB	Test System, Antineutrophil Cytoplasmic Antibodies (ANCA)	
	NST	Acetylcholine Receptor AutoAntibodies, Acetylcholine Blocking and Non-Blocking	
	NWG	Glutamic acid	

Regulation	Product Code	Name	Rationale for Exemption
		decarboxylase (GAD) AutoAntibodies	
	NBS	AutoAntibodies, lkm-1 (liver/kidney microsome,type 1)	
866.5660	NBO	AutoAntibodies, skin(desmoglein 1 and desmoglein 3)	The rationale for IVDs presented in this table is provided in Endnote #1.
	OEG	AutoAntibodies, skin (bullous pemphigoid 180 and bullous pemphigoid 230)	
	DBL	Multiple autoAntibodies, Indirect Immunofluorescence method, Antigen, Control	
	OCN	Insulin AutoAntibodies	
866.5750	DHB	Radioallergosorbent (RAST) Immunological Test System	
	MST	Gliadin Antibodies	
ANESTHESIOLOGY DEVICES			
868.1040	BSI	Powered Algesimeter	
868.1780	BXR	Inspiratory airway pressure meter	Exempt subject to design controls
868.1800	BXQ	Rhinoanemometer	Exempt subject to design controls. Note that the cables and leads standard

Regulation	Product Code	Name	Rationale for Exemption
868.1840	BZG	Diagnostic Spirometer	(AAMI/ANSI EC53:1995/(R) 2008 ECG cables and leadwires) applies to all patient-contacting cables and leads, independent of the exemption.
868.1850	BZK	Monitoring Spirometer	Exempt subject to design controls. Guidance for Peak Flow Meters for Over-the-Counter Sale
868.1860	BZH	Peak-Flow Meter for Spirometry	Exempt subject to design controls.
868.5130	BSN	Anesthesia Conduction Filter	Exempt subject to ISO 10993 and design controls.
868.5170	CCT	Laryngotracheal Topical anesthesia Applicator	Exempt subject to ISO 10993 and design controls.
868.5260	CAH	Breathing Circuit Bacterial Filter	Exempt subject to ISO 10993 and design controls. SO 8185 Third edition 2007-07-01 Corrected versions 2008-06-15 Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems
868.5270	BZE	Breathing System Heater	Exempt subject to ISO 10993, IEC 60601, and design controls. Third edition 2007-07-01 Corrected versions 2008-06-15 Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems
868.5650	CAO	Esophageal Obturator	Exempt subject to ISO 10993 and design controls.
868.5655	BYJ	Portable Liquid Oxygen Unit	Exempt subject to UL and IEC electrical standards and design controls.
	OGL	Portable Liquid Oxygen Unit	
	BYI	Powered Percussor	
868.5690	BWF	Incentive Spirometer	Exempt subject to ISO 10993 and design controls.
868.5880	CAD	Anesthetic Vaporizer	Exempt subject to UL and IEC electrical standards and design controls.

Regulation	Product Code	Name	Rationale for Exemption
CARDIOVASCULAR DEVICES			
870.1120	DXQ NPP OED	Blood Pressure Cuff	Exempt subject to FDA recognized standards and design controls: SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003/ (Manual, electronic or automated sphygmomanometers) AAMI/ANSI/ISO 81060-1:2007/ ISO 81060-1 First edition 2007-12-01: Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type Guidance Document: Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance Version 1; Final
870.1300	DQR	Catheter Cannula	Exempt subject to ISO 10993 and design controls.
870.1310	DRE	Vessel Dilator for Percutaneous Catheterization	Exempt subject to ISO 10993 and design controls.
870.1390	NMK	Trocar	Exempt subject to ISO 10993 and design controls.
870.1660	DXL	Indicator injector	Exempt subject to FDA recognized standards and design controls.
870.1670	DQF NKW	Syringe Actuator for an Injector	Exempt subject to FDA recognized standards and design controls.
870.4390	DWE	Cardiopulmonary Bypass Pump Tubing	Exempt subject to ISO 10993 and design controls.
870.4450	DXC MJN NMF	Vascular Clamp	Exempt subject to ISO 10993 and design controls.
870.4475	DWP	Surgical Vessel Dilator	Exempt subject to ISO 10993 and design controls.

Regulation	Product Code	Name	Rationale for Exemption
870.4875	DWX	Intraluminal Artery Stripper	Exempt subject to ISO 10993 and design controls.
870.4885	DWQ MGZ NLJ	External Vein Stripper	Exempt subject to ISO 10993 and design controls.
870.5800	JOW	Compressible Limb Sleeve	Exempt subject to ISO 10993, UL, and IEC electrical standards, and design controls.
DENTAL DEVICES			
872.1740	LFC NYH	Caries Detection Device	Exempt subject to ISO 10993, UL and IEC electrical standards, and design controls. ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.
872.1870	MVH	Sulfide Detection Device	Exempt subject to special controls (applicable standards) and design controls.
872.3200	KLE	Resin Tooth Bonding Agent	Exempt subject to ISO 10993 and design controls. ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
872.3250	EJK	Calcium Hydroxide Cavity Liner	Exempt subject to ISO 10993 and design controls. ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
872.3260	LBH	Cavity Varnish	Exempt subject to ISO 10993 and design controls. ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

Regulation	Product Code	Name	Rationale for Exemption
872.3275	EMA MZW NEA	Dental Cement	Exempt subject to ISO/ADA/ANSI standards 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 Guidance Document: Dental Cements - Premarket Notification; Final
872.3300	EBE	Hydrophilic Resin Coating for Dentures	Exempt subject to ISO standards and design controls. ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
872.3310	EBD	Coating Material for Resin Fillings	Exempt subject to ISO standards and design controls. ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

Regulation	Product Code	Name	Rationale for Exemption
872.3660	ELW	Impression Material	Exempt subject to ISO standards and design controls. ISO 13716 First edition 1999-05-01 Dentistry - reversible-irreversible hydrocolloid impression material systems ADA/ANSI Specification No.19 Dental - Elastometric Impression Material:2004 ISO 4823 Third edition 2000-12-15 Dentistry - Elastometric impression materials - Third Edition ISO 4823:2000 Technical Corrigendum 1 Published 2004-07-15 Dentistry - Elastomeric impression materials Technical Corrigendum 1 ISO 4823 Third edition 2000-12-15 Amendment 1 2007-07-01 Dentistry - Elastometric 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 1990-09-01 Dental alginate impression material ISO 1564 Second edition 1995-11-01 Dental aqueous impression materials based on agar Guidance Document: Dental Impression Materials - Premarket Notification; Final

Regulation	Product Code	Name	Rationale for Exemption
872.3690	EBF	Tooth Shade Resin Material	Exempt subject to ISO 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 Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff
872.3750	DYH KZP	Bracket Adhesive Resin and Tooth Conditioner	Exempt subject to ISO standards and design controls. ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

Regulation	Product Code	Name	Rationale for Exemption
872.3760	EBI	Denture Relining, Repairing, or Rebasing Resin	Exempt subject to ISO standards and design controls. ISO 10139-2 Second edition 2009-08-01 Dentistry - Soft lining materials for removable dentures - Part 2: Materials for long-term use ISO 10139-1:2005 Technical Corrigendum 1 2006-03-01 Dentistry - Soft lining materials for removable dentures - part 1; Materials for short-term use ANSI ADA Specification No.80 2001 (Reaffirmed 2007) Dental Materials - Determination of Color Stability ADA/ANSI Specification No. 12: 2002 (Reaffirmed 2008) Denture Base Polymers ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry ADA/ANSI Specification No.75 - Resilient Lining Materials for Removable Dentures, Part 1: Short-Term Materials: 1997 (Reaffirmed 2003) ADA Specification No.17 - Denture Base Temporary Relining Resins: 1983 (Reaffirmed 2006) ISO 10139-1 Second edition 2005-02-15 Dentistry - Soft lining materials for removable dentures - Part 1: Materials for short-term use
872.3765	EBC	Pit and Fissure Sealant and Conditioner	Exempt subject to ISO/ADA/ANSI 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 Guidance Document: Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff
872.3770	EBG	Temporary Crown and Bridge Resin	Exempt subject to ISO/ADA/ANSI standards and design controls. ANSI ADA Specification No.80 2001 (Reaffirmed 2007) Dental Materials -

Regulation	Product Code	Name	Rationale for Exemption
			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
872.3820	KIF NYD	Root Canal Filling Resin	Exempt subject to ISO/ADA/ANSI 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 ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
872.3920	ELL	Porcelain Tooth	Exempt subject to ISO/ADA/ANSI standards and design controls. ANSI ADA Specification No.38 2000 (Reaffirmed 2010) Metal-Ceramic Dental Restorative Systems ANSI ADA Specification No.80 2001 (Reaffirmed 2007) Dental Materials - Determination of Color Stability 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

Regulation	Product Code	Name	Rationale for Exemption
872.4120	DZH DZI DZJ KMW MXF	Bone Cutting Instrument and Accessories	Exempt subject to ISO and IEC 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
872.4475	EGM	Spring-Powered Jet Injector	Regulate as with other similar devices. ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
872.4840	ELB	Rotary Scaler	Exempt subject to ISO biocompatibility, IEC electrical standards, and design controls. ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

Regulation	Product Code	Name	Rationale for Exemption
872.4850	ELC NYC	Ultrasonic Scaler	Exempt subject to ISO biocompatibility, IEC electrical standards, and design controls. ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
872.5470	DYW NJM NLC NXC OYH	Orthodontic Plastic Bracket	Exempt subject to ISO biocompatibility, IEC electrical standards, and design controls. ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
872.5500	DZB	Extraoral Orthodontic Headgear	Exempt subject to ISO 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
	KKO	Teething Ring	Exempt subject to ISO standards and design controls. Certain teething rings are consumer products regulated by CPSC. ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

Regulation	Product Code	Name	Rationale for Exemption
872.6070	EBZ	Ultraviolet Activator for Polymerization	Exempt subject to ADA/ANSI standards, IEC electrical safety standards, and design controls. ADA/ANSI Specification No.48 Visible Light Curing Units; Guidance Document: Dental Curing Lights - Premarket Notification [510(k)] Submissions - Guidance for Industry and FDA Staff
872.6080	KOJ	Airbrush	Exempt subject to special controls and design controls. ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
872.6350	EAQ NXV	Ultraviolet Detector	Exempt subject to IEC electrical safety standards and design controls.
872.6660	EIH	Porcelain Powder for Clinical Use	Exempt subject to ANSI/ISO 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

Regulation	Product Code	Name	Rationale for Exemption
EAR, NOSE, AND THROAT DEVICES			
874.1090	ETY NAS	Auditory Impedance Tester	Exempt subject to ANSI Standards and design controls. Rx device used by healthcare professional in fitting Class I and Class II (510(k)-exempt) devices. ANSI S3.20 Bioacoustical Terminology ASA S3.39:1987 (Reaffirmed by ANSI May 18, 2007) Specifications for Instruments to Measure Aural Acoustic Impedance and Admittance (Aural Acoustic Immittance) ANSI S3.1 Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms ASA S12.2-2008 (Revision of ANSI S12.2-1995) American National Standard Criteria for Evaluating Room Noise
874.1120	ETS	Electronic Noise Generator for Audiometric Testing	Exempt subject to ANSI Standards and design controls. Rx device used by healthcare professional in fitting Class I and Class II (510(k) exempt).
874.4250	ERL	Ear, Nose, and Throat Electric or Pneumatic Surgical Drill	Propose exemption based on IEC 60601 and design controls.
GASTROENTEROLOGY DEVICES			
876.5220	KPL	Colonic Irrigation System	Exempt subject to Rx use, UL or IEC 60601, ISO 10993 and design controls. *Note - Class III for colon cleansing or lay use*.
876.5470	EZN	Ureteral Dilator	Exempt subject to ISO 10993 and design controls.
876.5520	FAH KOE	Ureteral Dilator	Exempt subject to ISO 10993 and design controls.
876.5665	NIH	Water Purification System for Hemodialysis	

Regulation	Product Code	Name	Rationale for Exemption
876.5980	EYN EZK FCB FGD FHT BSS FEF FEG FFW FPD	Gastrointestinal Tube and Accessories	Exempt subject to FDA recognized standards and design controls. AAMI/ANSI ID54:1996/(R)2005 Enteral feeding set adapters and connectors
876.5980	FRQ GBT KDH KGC KNT LCG PBP NGU	Gastrointestinal Tube and Accessories	Exempt subject to FDA recognized standards and design controls. AAMI/ANSI ID54:1996/(R)2005 Enteral feeding set adapters and connectors

Regulation	Product Code	Name	Rationale for Exemption
GENERAL AND PLASTIC SURGERY			
878.4040	MSH OKF OKG OKH OKI ONT OUK OXZ FXX FXY FYA FYB FYC	Surgical Apparel	Standards exist for barrier performance. AAMI/ANSI EC53:1995/(R) 2008 ECG cables and leadwires ASTM F2100-11 Standard Specification for Performance of Materials Used in Medical Face Masks ASTM F2101-07 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus* ASTM F1862-07 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) Guidance Document: Surgical Masks - Premarket Notification [510(k)] Submissions; Guidance for Industry and FDA

Regulation	Product Code	Name	Rationale for Exemption
878.4370	NZP LRO OJW	Surgical Drape and Drape Accessories	Standards exist for barrier performance. ASTM F2100-11 Standard Specification for Performance of Materials Used in Medical Face Masks ASTM F2101-07 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus* ASTM F1862-07 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) Guidance Document: Surgical Masks - Premarket Notification [510(k)] Submissions; Guidance for Industry and FDA
878.4410	NRB NRJ	Low Energy Ultrasound Wound Cleaner	Low Energy Ultrasound Wound Cleaner: Class II Special Controls Guidance Document - Guidance for Industry and FDA Staff
878.4630	FTC KGL	Ultraviolet Lamp for Dermatologic Disorders	Exempt subject to UL and IEC standards and design controls, however, must specify device in drug labeling.

Regulation	Product Code	Name	Rationale for Exemption
878.5070	FZG FZH FZI	Air-handling apparatus for a surgical operating room	Exempt subject to UL and IEC electrical standards and design controls.
878.5400	OLI	Low Level Laser System for Aesthetic Use	Special controls exist. Limit scope of exemption based on laser energy output.
GENERAL HOSPITAL AND PERSONAL USE DEVICES			
880.2910	FLL	Clinical Electronic Thermometer	Exempt subject to FDA recognized standards and design controls. ISO 80601-2-56 First Edition 2009-10-01 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement ASTM E1104-98 (Reapproved 2009) Standard Specification for Clinical Thermometer Probe Covers and Sheaths ASTM E1965-98 (Reapproved 2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature IEC 80601-2-59 (First edition - 2008) Medical Electrical Equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening CORRIGENDUM 111 ASTM E1112-00 (Reapproved 2011) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Guidance Document: Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers

Regulation	Product Code	Name	Rationale for Exemption
880.5025	KPE	I.V. Container	Exempt subject to ISO 10993 and design controls.
880.5430	KZE	Non-electrically Powered Fluid Injector	Exempt subject to ISO standard and design controls. ISO 21649 First edition 2006-06-01 Needle-free injectors for medical use -- Requirements and test methods8
880.5580	BWJ MQX NRW	Acupuncture Needle	Exempt subject to ISO 10993 and design controls.
880.6100	FLI	Ethylene Oxide Gas Aerator Cabinet	Exempt subject to FDA characterization of device type and design controls.
880.6260	NZJ ORW	Filtering Facepiece Respirator for Use B...	Exempt subject to standards and design controls. Note - These respirators are evaluated for effectiveness by the National Institute for Occupational Safety and Health (NIOSH) and are labeled "for occupational use."
880.6500	FRA MKB	Medical Ultraviolet Air Purifier	Exempt subject to FDA characterization of device type and design controls.
880.6600	OSZ	Antimicrobial Keyboard	Exempt subject to FDA characterization of device type and design controls.
880.6850	FRG KCT	Sterilization Wrap	Exempt subject to FDA recognized standards and design controls. Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA AAMI/ANSI ST77:2006/(R)2010 Containment devices for reusable medical device sterilization AAMI/ANSI ST24:1999/(R) 2009 Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities, 3ed.

Regulation	Product Code	Name	Rationale for Exemption
880.6870	KMH	Dry-Heat Sterilizer	Exempt subject to FDA recognized standards and design controls. AAMI/ANSI ST50:2004/(R)2010 Dry heat (heated air) sterilizers AAMI/ANSI ST40:2004/(R)2010 Table-top dry heat (heated air) sterilization and sterility assurance in dental and medical facilities, 2ed.
880.6880	FLE PEC	Steam Sterilizer	Exempt subject to FDA recognized standards and design controls. AAMI/ANSI ST8:2008 Hospital steam sterilizers AAMI/ANSI ST55:2010 Table-top steam Guidance Documents: Addendum to: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities Guidance on Premarket Notification 510(k) for Sterilizers Intended for Use in Health Care
880.6920	KZH	Syringe Needle Introducer	Exempt subject to FDA recognized standards and design controls. ISO 11608-1 Second edition 2012-04-01 Needle-based injection systems for medical use - Requirements and test methods - Part 1: Needle-based injection systems ISO 11608-2 Second edition 2012-04-01 Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles ISO 23908 First edition 2011-06-11 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling ISO 11608-4:2006 Pen-injectors for medical use -- Part 4: Requirements and test methods for electronic and electromechanical pen-injectors ISO 11608-3 First edition 2000-12-15 Pen-injectors for medical use - Part 3: Finished cartridges - Requirements and test methods

Regulation	Product Code	Name	Rationale for Exemption
NEUROLOGICAL DEVICES			
882.1020	GZM	Rigidity analyzer	Exempt subject to design controls.
882.1275	GYB	Electroconductive Media	Exempt subject to ISO 10993 and design controls.
882.1570	HCS	Powered Direct-Contact Temperature Measurement Device	Exempt subject to UL and IEC electrical standards and design controls.
882.4150	HBO	Scalp Clip	Exempt subject to ISO 10993 and design controls.
882.4175	HCI	Aneurysm Clip Applier	Exempt subject to UL and IEC electrical standards, ISO 10993, and design controls.
882.4275	GZQ	Dowel Cutting Instrument	Exempt subject to UL and IEC electrical standards, ISO 10993, and design controls.
882.4300	HBG NLO	Manual Cranial Drills, Burrs, Trephines, and their Accessories	Exempt subject to ISO 10993 and design controls.
882.4305	HBF NLP	Powered Compound Cranial Drills, Burrs, Trephines and their Accessories	Exempt subject to UL and IEC electrical standards, ISO 10993, and design controls.
882.4310	HBE NLN	Powered Simple Cranial Drills, Burrs, Trephines and their Accessories	Exempt subject to UL and IEC electrical standards, ISO 10993, and design controls.
882.4360	HBC	Electric Cranial Drill Motor	Exempt subject to UL and IEC electrical standards, ISO 10993, and design controls.
882.4370	HBB	Pneumatic Cranial Drill Motor	Exempt subject to UL and IEC electrical standards, ISO 10993, and design controls.

Regulation	Product Code	Name	Rationale for Exemption
882.4460	HBL	Neurosurgical Head Holder (Skull Clamp)	Exempt subject to ISO 10993 and design controls.
882.4700	HBA	Neurosurgical Paddie	Exempt subject to ISO 10993 and design controls.
882.4840	HAE	Manual Rongeur	Exempt subject to ISO 10993 and design controls.
882.4845	HAD	Powered Rongeur	Exempt subject to UL and IEC 60601, ISO 10993, and design controls.
882.5070	JXL	Bite Block	Exempt subject to ISO 10993 and design controls. Note - Bite blocks for airway management are Class I exempt.
882.5175	HCE	Carotid Artery Clamp	Exempt subject to ISO 10993 and design controls.
882.5900	GXO	Preformed Craniosynostosis Strip	Exempt subject to ISO 10993 and design controls.
882.5960	HAX	Skull Tongs for Traction	Exempt subject to ISO 10993 and design controls.
OBSTETRICAL & GYNECOLOGICAL DEVICES			
884.1100	HFE	Endometrial Brush	Exempt subject to special controls and design controls.
884.3900	HDX HFK KXP	Vaginal Stent	Exempt subject to ISO 10993 and design controls.
884.4900	HDD HEA HHP KNC	Obstetric Table and Accessories	Exempt subject to UL and IEC electrical standards and design controls.
884.5160	HGX OHH	Powered Breast Pump	Exempt subject to UL and IEC electrical standards and design controls.

Regulation	Product Code	Name	Rationale for Exemption
884.5970	NBV	Clitoral Engorgement Device	Exempt subject to existing special controls.
OPHTHALMIC DEVICES			
886.1300	NJG	Afterimage Flasher	Exempt subject to Electrical standards (UL and IEC) and design controls.
886.1630	HLX	AC-Powered Photostimulator	Exempt subject to Electrical safety standards (UL and IEC) and design controls.
886.4610	LCC	Ocular Pressure Applicator	Exempt subject to ISO biocompatibility standards (ISO 10993) and design controls.
ORTHOPEDIC DEVICES			
888.1240	LBB	AC-Powered Dynamometer	Propose for exemption. Electrical safety standards and design controls. No 510(k) have been submitted for years.
888.4580	JDX LZV	Sonic Surgical Instrument and Accessories	Exempt subject to Electrical safety standards (UL and IEC) and design controls. Technology is the same as is used on non-medical uses. ASTM F 565-04 (Reapproved 2009)e1 Standard Practice for Care and Handling of Orthopedic Implants and Instruments8
PHYSICAL MEDICINE			
890.3110	INO	Electric Positioning Chair	Exempt subject to IEC 60602 electrical standard and design controls.
890.3690	INK	Powered Wheeled Stretcher	Exempt subject to IEC 60602 electrical standard, FDA guidance, and design controls. Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment - Guidance for Industry and FDA Staff

Regulation	Product Code	Name	Rationale for Exemption
890.3800	INI	Motorized Three-Wheeled Vehicle	Exempt subject to ISO standards and design controls.*
890.3860	ITI	Powered Wheelchair	Exempt subject to ISO standards and design controls.*
890.3880	IQC	Special Grade Wheelchair	Exempt subject to ISO standards and design controls.*
890.3900	IPL	Standup Wheelchair	Exempt subject to ISO standards and design controls.*
890.3930	ING	Wheelchair Elevator	Exempt subject to This is nothing more than a daily assist device. ISO standards and design controls. [iv]
890.5150	ILK	Powered Patient Transport	Exempt subject to ISO standards, FDA guidance, and design controls. Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment - Guidance for Industry and FDA Staff
890.5250	IMB	Moist Steam Cabinet	Exempt subject to standards, including UL and IEC electrical standards that can be factored into Design Controls. Similar products are available as consumer products.
890.5500	NZY ILY IOB NHN ONH OAP	Infrared Lamp	Exempt subject to Electrical safety standards (UL/IEC), labeling (e.g., "WARNING: Use carefully. May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of ..... by children or incapacitated persons may be dangerous," and design controls.
			Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices
890.5650	IRP	Powered Inflatable Tube Massager	Exempt subject to Electrical safety standards (UL/IEC) and design controls.
890.5880	JFB	Multi-Function Physical Therapy Table	Exempt subject to Electrical safety standards (UL/IEC) and design controls.

Regulation	Product Code	Name	Rationale for Exemption
890.5900	ITH	Power Traction Equipment	Exempt subject to Electrical safety standards (UL/IEC) and design controls.
RADIOLOGY DEVICES			
892.1360	KPT	Radionuclide Dose Calibrator	Exempt based on the existence of FDA recognized standards and existing FDA product specific guidance. IEEE N42.13-2004 Calibration and Usage of "Dose Calibrator" Ionization Chambers for the Assay of Guidance Document: Guidance for the Submission of Premarket Notifications for Radionuclide Dose Calibrators; Final
892.1660	JAB	Non-Image-Intensified Fluoroscopic X-Ray...	Exempt based on the existence of FDA recognized standards and existing FDA product specific guidance. NEMA XR7-1995 (R2000) High-Voltage X-Ray Cable Assemblies and Receptacles8
892.2030	LMA	Radiological Image Digitizer	
892.5770	JAI	Powered Radiation Therapy Patient Support Assembly	Exempt based on IEC 60601 and design controls.

[i] From AdvaMed's September 2009 report entitled "Risk Assessment of IVD Test Systems Identification of Candidates for 510(k) Exemption an IVD medical device may be exempted from 510(k) requirements if all of the following criteria are met.

1. The clinical application of the test results is well established.
2. The test system's performance characteristics are well established.
3. The laboratory use and quality control of the test system are regulated under CLIA regulations.
4. Changes in performance characteristics that could affect safety and effectiveness either:
   a. will be detected by users, using control mechanisms integral to the device and/or conventional laboratory control procedures, before exposing patients to harm
   or

b. will not cause serious injury or lead to a life-threatening situation for a patient (e.g., due to an incorrect diagnosis or inappropriate treatment).

5. Device malfunctions or use errors would not present a public health hazard or lead to a high degree of morbidity or mortality.
6. The device does not have a history of adverse events associated with failures to meet its performance specifications or otherwise perform as intended.
7. The device conforms to Special Controls specified by the FDA in Guidance Documents. for example, where appropriate to provide additional assurance of safety and effectiveness, FDA could specify :
   a. minimum analytical performance specifications and/or product standards;
   b. traceability of calibrator values to a recognized reference material/reference measurement procedure;
   c. evaluation protocols for validating analytical performance claims;
   d. device-specific design or manufacturing requirements
   and/or
   e. specific risk mitigation information in the instructions for use.

An exemption would not apply if any one of the following were true:
1. The IVD medical device is intended for a substantially different medical purpose than the intended use described in the classification regulation;
2. The IVD medical device is intended for a medical purpose specifically excluded from exemption;
3. The IVD medical device is based on a novel technology that has not been previously cleared or approved by FDA
   or
4. The IVD medical device is based on a method principle that is specifically excluded from exemption.

[ii] FDA did not address any devices regulated by OIR in this draft guidance document.

[iii] The use of these devices does not "prevent" impairment to human health and their use is not associated with a potential unreasonable risk of illness or injury (see Section 510(l) of the Federal Food, Drug and Cosmetic Act (21 USC Chapter 9).

[iv] *ISO 7176-11:1992 Wheelchairs - Part 11: Test dummies
ISO 7176-13:1989 Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
ISO 7176-15:1996 Wheelchairs - Part 15: Requirements for information disclosure, documentation and labeling
ISO 7176-16:1997 Wheelchairs - Part 16: Resistance to ignition of upholstered parts -- Requirements and test methods
ISO 7176-6:2001 Wheelchairs - Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
ISO 7176-3:2003 Wheelchairs - Part 3: Determination of effectiveness of brakes
ISO 7176-1:1999 Wheelchairs - Part 1: Determination of static stability
ISO 7176-2:2001 Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs
ISO 7176-4:2008 Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
ISO 7176-5:2008 Wheelchairs - Part 5: Determination of overall dimensions, mass and manoeuvring space
ISO 7176-10:2008 Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs

ISO 7176-14:2008 Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
ISO 7176-21:2009 Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
ISO 7176-9: Third edition 2009-11-15 Wheelchairs - Part 9: Climatic tests for electric wheelchairs
ANSI/RESNA WC-1:2009 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 1 Determination of static stability
ANSI/RESNA WC-2:2009 American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 2: Determination of dynamic stability of electrically powered wheelchairs
ANSI/RESNA WC-2:2009 American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 3: Determination of effectiveness of brakes
ANSI/RESNA WC-2:2009 Section 4: Energy consumption of electrically powered wheelchairs and scooters for determination of theoretical dis
ANSI/RESNA WC-1:2009 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 5: Determination of dimensions, mass and maneuvering space
ANSI/RESNA WC-2:2009 American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 6: Determination of maximum speed, acceleration and deceleration of electrically powered wheelchairs
ANSI/RESNA WC-1:2009 American National Standard for Wheelchairs ¿ Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 7: Method of Measurement of Seating and Wheel Dimensions
ANSI/RESNA WC-1:2009 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 8: Requirements and test methods for static, impact and fatigue strengths32
ANSI/RESNA
ANSI/RESNA WC-2:2009 American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 9: Climatic tests for electrically powered wheelchairs
ANSI/RESNA WC-2:2009 American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
ANSI/RESNA WC-1:2009 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 11: Test dummies
ANSI/RESNA WC-1:2009 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 13: Determination of coefficient of friction of test surfaces
ANSI/RESNA
ANSI/RESNA WC-2:2009 American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 14: Power and control systems for electrically powered wheelchairs ¿ Requirements and test methods
ANSI/RESNA
ANSI/RESNA WC-1:2009 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 15: Requirements for information disclosure, documentation and labeling

ANSI/RESNA WC-1:2009 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 16: Resistance to ignition of upholstered parts - Requirements and test methods46
ANSI/RESNA WC-1:2009 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 22: Set-up procedures
ANSI/RESNA WC-2:2009 Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and
ANSI/RESNA WC-1:2009 American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 26: Vocabulary
A18.1-2011 (Revision of ASME A18.1-2008) Safety Standard for Platform Lifts and Stairway Chairlifts

Guidance Document Guidance: Document for the Preparation of Premarket Notification [510k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles