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April 6, 2018

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

Re: Docket No. FDA-2017-N-4301: Fostering Medical Innovation: A Plan for Digital Health Devices; Software Precertification Pilot Program

To Whom It May Concern:

The Advanced Medical Technology Association ("AdvaMed") appreciates the opportunity to provide input on the Food and Drug Administration's ("FDA" or "Agency") Digital Health Software Precertification ("Pre-Cert") Program. AdvaMed represents manufacturers of digital health technologies, medical devices, and diagnostic products 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 and companies.

We commend FDA for its ongoing efforts to create a Pre-Cert Program. If properly developed and implemented, the Pre-Cert Program has the potential to reduce pre- and post-market burdens for both software developers and FDA, and to enable streamlined changes and modifications to software.

AdvaMed has developed the attached Strawman for FDA's consideration and use in developing the parameters of the Pre-Cert Program. We believe the items described in the Strawman represent a starting point for establishing robust policies and procedures to enable the Pre-Cert Program to be of maximum benefit to patients, medical technology manufacturers, and FDA.

* * *

AdvaMed would like to thank the FDA for its consideration of these comments and looks forward to continuing to work with the Agency on these important issues. Please do not hesitate to contact me at 202-434-7224 or zrothstein@advamed.org if you have any questions.

Respectfully submitted,

/s/

Zachary A. Rothstein, Esq.
Associate Vice President
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Attachment

AdvaMed Pre-Certification Program Strawman

April 6, 2018

Medical device software presents unique oversight challenges for the U.S. Food and Drug Administration ("FDA" or "Agency"). While historically regulated in the same manner as hardware-based medical devices, software is designed, developed, modified and surveilled in different ways. To ensure an appropriate form of oversight is exercised for these technologies, an evolution in the Agency's regulatory approach is needed. In this regard, the medical device industry commends FDA's efforts to develop a Pre-Certification Program ("Pre-Cert"). We believe a Pre-Cert Program, if implemented correctly, could substantially streamline FDA's capabilities to exercise its regulatory oversight of software technologies while providing manufacturers more appropriately designed pre- and post-market requirements.

Below we offer our general considerations about how the Pre-Cert Program should operate:

- General
    - The Program should apply to all Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD), including but not limited to artificial intelligence and machine learning programs.
    - The Program should address, using a least burdensome approach, various structural and organizational circumstances that may occur with a qualified firm, such as when technologies are acquired by a Pre-Cert qualified company from a non-Pre-Cert qualified company, when a Pre-Cert qualified company contracts with a third party to develop all or a portion of the software, and when a Pre-Cert qualified company's software interacts (e.g. is interoperable) with a non-Pre-Cert qualified company's device.
    - The Program's requirements should be clearly communicated to the public.
- Certification Considerations
    - Certification scoring results should be kept confidential.
    - Assessment results should be used only for purposes of the Program.
    - Should certification be performed by qualified third party organizations, FDA should establish robust guidelines and training programs to ensure such a system is structured objectively and implemented consistently. Third party certifiers should be subject to a periodic recertification process. Such certification processes and guidelines should include opportunity for public input before being implemented by FDA.
    - Program certification should be based on the firm, not an individual. A flexible approach should be used so that a firm can determine whether to apply for certification for the entire company, select sites, specific business units, or based on other organizational boundaries.
    - Certification of manufacturers should also be subject to periodic renewal.
- Premarket
    - The Program should reduce the complexity of the premarket process for initial submissions based on a risk assessment and other relevant criteria.
        - For software technologies subject to the Agency's 510(k) review program, the Program should, at a minimum, provide an exemption or streamlined premarket review and modification of submission requirements (e.g. Agency notification).
        - For software technologies that require PMA, the Program should, at a minimum, offer a streamlined process for the software-related portions of such submissions and required supplements, such as communicating software modifications through annual reports.

        - Pre-Cert qualified companies that maintain device masterfiles for PMA products developed by non-Pre-Cert qualified companies should receive a similar streamlined process.
    - Tiered Qualification Criteria
        - All companies granted Pre-Certification should meet a baseline of organizational excellence. However, multiple levels of the Pre-Cert program could be beneficial. This would enable companies to be Pre-Certified as start-ups, while enabling companies to attain higher levels of Pre-Cert with greater benefits as they prove their ability to develop and introduce high quality products to market. Such an approach would ensure greater patient safety, while at the same time providing more rapid innovation. For example, a basic three-level system could be organized as follows, with each tier requiring further evidence of organizational excellence:
            - Tier 1
                - Under Tier 1, if a firm does not have experience developing and introducing moderate risk regulated software products, a firm's new products subject to 510(k) premarket notification submission (or de novo request) would, before going to market, require a 510(k) through the new streamlined process.
            - Tier 2
                - Under Tier 2, once a firm has shown a history of developing and introducing high quality moderate risk products, future moderate risk products would not be required to submit a 510(k) submission. We would propose notification still be required to meet the statutory requirement (unless changed).
            - Tier 3
                - Under Tier 3, once a firm has shown a history of developing and introducing high quality high risk products, future software-related portions of PMAs and Masterfile submissions would be streamlined, and modifications would be provided in an annual report.
        - Program Participants would be expected to maintain their designated qualification level or face penalties, such as a downgrade of their Tier status.
- Postmarket
    - The Program should reduce the complexity of the submission process for product changes based on a risk assessment and other relevant criteria and allow the manufacturer to use their certified process to initiate necessary software changes in a timely and efficient manner. Specifically, the Program should allow manufacturers to issue software modifications and other updates before, or in conjunction with, any required reports to the FDA to ensure users receive such updates as quickly as possible.
    - The Program should provide exemption from or streamlined malfunction reporting requirements; criteria should unambiguously describe situations in which streamlined reporting is not acceptable (e.g., in the case of an adverse event).
    - Additionally, conditions where reporting is not required should be emphasized, such as in the case of product required security updates, without a related hazard, or harm, causing incident.
    - Based on the requirements for obtaining Pre-Certification, consideration should be given to the applicability to inspections (e.g. MDSAP, Case for Quality, QSIT, etc.).

- As with the premarket activities, the level of Agency oversight in relation to various postmarket aspects (such as modifications reporting requirements) should be linked to a manufacturer's tier.