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Marketing Clearance of Diagnostic Ultrasound Systems and Transducers

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Agenda

- Objectives and Background
- Highlights of the Final Guidance Document
- Scope
- Compliance Policy
- Transducer Element Check
- Updated Consensus Standards and Guidance Documents
- Key Take-Aways
- Examples of Compliance Policy Applications
- Resources and Questions

Objectives

- Understand the regulatory history of diagnostic ultrasound devices
- Become familiar with the landscape of ultrasound industry, and understand the recent technological advancements
- Understand the difference between the previous final guidance document issued in 2008 and the revised guidance document, published June 27, 2019: https://www.fda.gov/media/71100/download
- Become familiar with the new regulatory evaluation

Background

- Diagnostic ultrasound is a pre-amendment device
- Most diagnostic ultrasound devices receive marketing clearance from the FDA through the 510(k) process
- The FDA issued the first diagnostic ultrasound guidance in mid-1980's
- Next guidance about diagnostic ultrasound devices version was issued Sept. 9, 2008
- On June 27, 2019, the FDA issued a revised final guidance: "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, Guidance for Industry and Food and Drug Administration Staff"

Final Guidance Document Highlights

- Compliance Policy: The FDA does not intend to enforce compliance with the 510(k) requirement for certain modified ultrasound and transducer devices (that have already obtained an initial 510(k) clearance) when certain conditions apply

- Transducer Element Check: Integrated tests of transducer performance each time a transducer is connected to the main system or activated

- Updated Consensus Standards

- Updated FDA Guidance Documents

Final Guidance Scope

- This guidance:
  - Supersedes the FDA's 2008 guidance "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers"
  - Describes the types of modifications to a diagnostic ultrasound device for which FDA does not intend to enforce the requirement for a new premarket notification (510(k)) -- the 2008 guidance had specified a new 510(k) for these types of modifications
  - Includes a new transducer element check that applies to all ultrasound devices covered in this guidance

Compliance Policy

- The FDA does not intend to enforce compliance with the 510(k) requirement for certain modified ultrasound and transducer devices (that have already obtained an initial 510(k) clearance) when the following apply:

  - The intended use of the modified device is not changed
  - The device is not a reusable device subject to the requirement for the submission of reprocessing labeling and validation data
  - The modes of operation for the modified device are well-established
  - The modifications do not lead to acoustic outputs that exceed the recommended maximum acoustic output levels
  - The modifications do not result in a range of ultrasound interrogation parameters outside a well-known range, specified in the guidance document

Compliance Policy (Continued)

- The FDA does not intend to enforce compliance with the 510(k) requirement for certain modified ultrasound and transducer devices (that have already obtained an initial 510(k) clearance) when the following apply:

  - The modifications do not utilize novel mechanical or thermal effects for imaging or measurements
  - The measurements and analyses are clearly described and the user can adjust the associated control parameters
  - Transducer element check is performed
  - Transducer surface temperature falls within a well-defined range, and
  - Appropriate transducer covers are recommended to users

Transducer Element Check

- Integrated tests of transducer performance each time a transducer is connected to the main system or activated

- The transducer performance test should be accessible by competent technical personnel, such as operators or service personnel

- While the FDA appreciates that different performance specifications may be necessary for transducers based on the application and system configuration, each device should include some level of testing. For example, an impedance check of each transducer element may provide a preliminary evaluation of the element integrity and function.

Transducer Element Check (Continued)

- Device manufacturers implement methods to communicate the results of the transducer performance tests to the operators, and identify regions of the image that have been compromised by transducer malfunction

- This integrated test feature would also generate a report on the performance of the probe under test for documentation, generally including a list of elements or smallest available patches of elements that have been compromised

- This integrated test should also be available to the operators to initiate any time when a particular probe is suspected of failure

Updated Consensus Standards

- Output Display Standard: IEC 60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2015
- IEC 62359 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017
- IEC 62127-1 Ultrasonics -- Hydrophones -- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz., 2013
- IEC 62127-1 Ultrasonics -- Hydrophones -- Part 2: Calibration for ultrasonic fields up to 40 MHz, *Annex I*, 2013
- ES60601-1 Medical electrical equipment—Part 1: General requirements for basic safety and essential performance, 2005/(R)2012 and A1:2012
- IEC 60601-1-2 Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance –Collateral standard: Electromagnetic disturbances –Requirements and tests, 2014

- **Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, dated September 14, 2018**

Updated Guidance Documents

- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, dated September 14, 2018: https://www.fda.gov/media/71983/download
- Deciding When to Submit a 510(k) for a Software Change to an Existing Device, dated October 25, 2017: https://www.fda.gov/media/99785/download
- Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program, dated May 7, 2019: https://www.fda.gov/media/114034/download
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, dated March 17, 2015: https://www.fda.gov/media/80265/download
- Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices, dated July 11, 2016: https://www.fda.gov/media/94758/download
- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, dated January 21, 2016: https://www.fda.gov/media/74445/download
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, dated October 2014: https://www.fda.gov/media/86174/download

Key Take-Aways

Compliance Policy:

The revised final guidance enables manufacturers with an established track record of ultrasound device development, via submission of 510(k)s for their original devices, to add new safety features and make certain modifications to address clinical needs without the need to submit another 510(k).

Key Take-Aways (Continued)

- The new transducer element check provides a mechanism for users to test possible degradation due to aging and ensure continued safety and effectiveness
- Reduce review of modifications with established history of safety and effectiveness
- Transition Period: The guidance is effective immediately. Please note that guidance documents represent FDA's recommendation. Manufacturers should address the recommendations.
- There will be presentations at professional societies

Examples of Compliance Policy Applications

- Adding Continuous-Wave (CW) and Pulsed-Wave (PW) Doppler interrogation methods to the modes of operation of the device.

- Adding an algorithm that measures the volume of an organ based on scientifically well-established image segmentation and volume calculation methods. The scientific basis of the algorithm should be disclosed to the users for optimal usage of the measurement.

- Adding a new transducer with similar indications for use and similar acoustic output as one already cleared in the system. The new transducer may have a new clinical application, if the particular clinical application (e.g., indication) has been cleared for another transducer, manufactured by the same manufacturer.

- Adding a B-mode noise reduction filter for general imaging use to a system. The characteristics of the algorithm used for the noise reduction are defined.

Resources

- “Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, Guidance for Industry and Food and Drug Administration Staff,” dated June 27, 2019: https://www.fda.gov/media/71100/download

Questions?

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