Achieving the Quadruple Aim with AI-Guided Ultrasound Systems in Clinical Settings: Using the Current Ultrasound Premarket Guidance - Benefits and Challenges

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Key Questions

- How will AI impact Imaging Modalities?
- Who will Benefit?
- Is there a Regulatory Framework in Place to Support Innovators?
- Conclusions and Takeaways
Ultrasound is Good for Public Health

- Imaging modality used for decades
- Non-ionizing radiation
- Real-time image capture and display
- Safety through image guidance – eliminating risks associated with invasive procedures
- Ultrasound used by clinicians to guide a wide variety of procedures previously done “blindly”¹
- Expanded use in General Practice²

Technology Has Come a Long Way

Then

Now
AI in Ultrasound

AI is designed to enhance human intelligence and the patient-physician relationship rather than replace it\(^3\)

Who Benefits?

How are Hospitals Measured?

Success is measured on quality and patient outcomes rather than the number of visits, tests or procedures.
How do we get there?

A Closer Look at:

• Regulatory framework for Diagnostic Ultrasound Systems
  - Does addition of AI fit within existing framework?
• Medical Device Development Methodology
  - Quality System Regulations and Use of Standards
    • Where does AI fit in?
Existing Market Authorization Pathways

Current Medical Device Pathways

Low Risk Class I
- General Controls

Moderate Risk Class II
- General Controls
- Special Controls
- Ultrasound Systems
- 510(k) Premarket Notification

High Risk Class III
- General Controls
- Premarket Approval
- Premarket Authorization + IDE

Unknown Classification/Default Classification = Class III

predicate for device?

Yes

de novo

No

Yes

High Risk Device?

No
Algorithms in Ultrasound Machines Today

- Conventional Algorithms are currently used in ultrasound machines
  - The pathway for regulatory clearance is no different
  - The submission elements are consistent
    - Claims, intended use, labeling, performance characteristics
  - Today datasets are used for ‘fine tuning’ parameters of algorithms
    - Image processing using conventional algorithms can perform the same function as image processing using AI algorithms (ex. Edge Detection)
  - Development process does not change (use of verification and validation is consistent)
Conceptual V-Model Development Process

- PMS
- Final Product System with AI Algorithm (locked to SW Version)
- Modifications, Updates, Maintenance
- Start of data collection
- Test Dataset (not used in development)
- Tuning Dataset (used to optimize algorithm)
- Training Dataset (used to develop algorithm)
- System Requirements (includes AI Requirements)
- System Verification
- Integration Test
- Verification
- Validation
- User Needs
- System Verification
- User Needs
- Architecture/Detailed Design
- Integration Test
- Verification
- Training Dataset
- Tuning Dataset
- AI Algorithm
- 1. Training
- 2. Optimizing
- Validation
- User Needs
Diagnostic ultrasound systems are intended to provide images of or signals from the inside of the body, and FDA recommends that they be indicated for such use accordingly.

Operator qualifications and device use settings should be specified in the IFU statement.

- Description of device
- Indications for use, contraindications, warnings, precautions, adverse effects, instructions for use, summaries of clinical studies, and references

Defined and specified in IFU

- Design Controls
  - Design Validation 21CFR820.30(g)
  - Risk Management

- Indication for Use

- Device Description

- Predicate Device Description

- Acoustic Output Reporting

- General Clinical Safety and Effectiveness

- Labeling

- Track 1 Recommendations

- Track 3 Recommendations
Key Takeaways

• Existing marketing authorization pathways are clear, effective and predictable for innovators – while continuing to ensure safety & effectiveness

• The medical imaging industry has already started to develop standards for AI technologies to support public health.

• Development of consensus standards, such as DICOM, ISO, IEC, etc, through private-public partnerships has already proven effective.

• Continued development and access to AI Algorithms by clinicians will provide them with devices needed to achieve the Quadruple AIM.
Thank You