End-to-End 510(k) Clearance for Imaging-Based SaMD Device

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OVERVIEW

Elexes supported a medical technology company developing a Software as a Medical Device (SaMD) solution that analyzes X-ray images to detect the prevalence of respiratory diseases. The device involved complex image-processing algorithms, AI-enabled diagnostics, and integration with existing hospital workflows, all requiring a comprehensive regulatory strategy to meet FDA expectations for Class II imaging-based devices.

The client needed end-to-end FDA 510(k) support, from regulatory strategy through dossier preparation, eSTAR formatting, and direct interactions with the FDA, while ensuring speed, quality, and compliance with all relevant standards.

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KEY CHALLENGES

- **Clinical & Technical Documentation:** Aligning retrospective image analysis studies with FDA clinical evidence expectations while managing patient data privacy and protocol co-authoring for image annotation.

- **Risk Management & Testing:** Developing a risk-based validation plan aligned with ISO 14971, IEC 62304, IEC 62366, and cybersecurity standards like FDA's Content of Premarket Submissions for Cybersecurity guidance.

- **Regulatory Interactions:** Preparing for and addressing Refuse-to-Accept (RTA) and Additional Information (AI) requests to keep the submission on track.

- **Complex Algorithms:** Demonstrating software verification and validation (V&V) evidence per FDA guidance for AI/ML-enabled devices.

ELEXES' APPROACH

Elexes deployed a multi-disciplinary team of regulatory strategists, biomedical engineers, and software validation experts to deliver:

1. Regulatory Strategy & Predicate Device Analysis

- Conducted a gap analysis of technical documentation and testing protocols.
- Identified suitable predicate devices and established a substantial equivalence strategy early in the process.
- Prepared a detailed regulatory pathway including timelines for each milestone.

2. Technical Documentation & Testing Readiness

- Reviewed and co-authored clinical study protocols for retrospective X-ray image datasets.
- Designed a verification & validation plan covering software functionality, image accuracy metrics, and cybersecurity penetration testing requirements.
- Ensured all testing followed FDA-recognized consensus standards for imaging systems.

ELEXES' APPROACH

3. End-to-End 510(k) Submission Management

- Prepared the complete 510(k) dossier with all required sections, labeling, software documentation, and risk assessments.
- Used FDA's eSTAR format to streamline submission quality and reduce review delays.
- Managed RTA and AI interactions with the FDA, providing clarifications within days to ensure the FDA review proceeds without interruption.

4. Regulatory Communication & Clearance

- Coordinated all communication with the FDA, ensuring consistent messaging on clinical evidence and testing outcomes.
- Achieved successful clearance well within projected timelines, enabling the client's U.S. market entry as planned.

RESULTS & IMPACT

- **Clearance Timeline:** 510(k) clearance achieved 3 months ahead of the original schedule despite additional FDA AI requests.
- **Quality Outcomes:** Zero major deficiencies during RTA and AI phases due to upfront gap analysis and early testing alignment.
- **Regulatory Confidence:** FDA reviewers highlighted the robustness of the submission package, especially the clinical evidence strategy and software validation approach.

BROADER RELEVANCE TO IMAGING & DIAGNOSTIC DEVICES

Elexes' expertise on this project directly applies to imaging and diagnostic devices such as:

- Whole-body DXA systems for bone mineral density and body composition analysis
- Dental X-ray sensors and intraoral imaging devices
- AI-powered radiology software for CT, MRI, and ultrasound diagnostics
- Wearable cardiac and respiratory monitoring devices with imaging capabilities
- Non-invasive imaging tools integrating software analytics and cloud-based diagnostics

The same end-to-end regulatory rigor, from risk management and testing strategy to clinical protocol review and 510(k) dossier preparation, has helped multiple imaging device manufacturers accelerate FDA clearance and reduce regulatory risk while maintaining quality and compliance.

WHY THIS MATTERS FOR IMAGING DEVICE MANUFACTURERS

This case study demonstrates Elexes' ability to:

- Align clinical protocols and testing plans with FDA expectations early.
- Handle complex imaging algorithms and AI/ML validation requirements confidently.
- Manage the entire 510(k) process from start to finish with a focus on speed and quality.
- Ensure smooth FDA interactions, minimizing delays from RTA or AI requests.
- Whether for advanced radiology software, DXA systems, or dental imaging devices, Elexes brings the same structured, experienced, and results-driven approach to every project.

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