Elexes | SaMD Regulatory Support Snapshot

Company Overview

Elexes is a global regulatory and quality compliance consulting firm with over a decade of experience supporting medical device and digital health companies.

We specialize in Class II SaMD, AI/ML-enabled tools, and connected devices across the U.S., EU, Canada, and other regulated markets.

Elexes

Core Expertise for Class II SaMD:

- Regulatory strategy and classification analysis
- Pre-submission (Q-Sub) meeting preparation
- 510(k) submission planning and authoring
- Clinical evaluation and software documentation per FDA expectations
- Cybersecurity, interoperability, and usability compliance
- Risk management aligned with ISO 14971 and IEC 62304
- End-to-end project management to ensure on-time clearance

Selected SaMD Project Experience:

- **Cognitive Decision Support Tool (U.S.)**
  - Class II SaMD integrating with EHR
  - Achieved 510(k) clearance in under 4 months post-submission
- **Remote Patient Monitoring App (U.S./Canada)**
  - Class II mobile app with cloud-based analytics
  - Developed a complete FDA and HC submission dossier
- **AI-based ECG Interpretation Tool (U.S./EU)**
  - MDR compliance + FDA pre-sub pathway
  - Technical documentation + performance evaluation for SaMD

Why Elexes?

- 100% success rate in 510(k) submissions over the past 36 months
- Deep domain expertise in digital health and SaMDs
- Strategic, hands-on partnership with dedicated regulatory leads

We appreciate the opportunity to support Eden's mission and look forward to collaborating on the Eden Suite submission.