CASE STUDY

FDA Pre-Submission & Clearance Support for an Oxygen-Delivery and Respiratory Training System

Elexes

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Problem Statement

A MedTech company developing an oxygen-delivery and respiratory training system approached Elexes for end-to-end regulatory support to bring its novel device to the U.S. market.

The system alternated between controlled oxygen and room-air cycles to improve cardiopulmonary performance in patients recovering from respiratory illnesses or surgery.

Because the product introduced dynamic oxygen modulation and closed-loop feedback using pulse oximetry, it did not fit neatly within existing FDA-cleared device categories like CPAPs or concentrators.

The client needed to:

- Confirm classification and submission pathway (510(k) vs. De Novo)
- Define testing and validation expectations for oxygen cycling accuracy, safety, and patient contact materials
- Build a risk-based, FDA-aligned strategy to avoid delays and unnecessary testing

Key Challenges

Dynamic Oxygen Control & Safety Validation: The device actively adjusted oxygen levels in real time, requiring justification of control algorithms, cycle stability, and patient safety under hypoxic or hyperoxic conditions.

Hybrid Predicate Uncertainty: Existing CPAP and oxygen concentrator predicates had different intended uses and risk profiles. They needed the FDA's feedback to determine the most appropriate path.

Software & Sensor Integration: The closed-loop feedback mechanism utilized SpO_2 sensors and microcontroller-based algorithms, which raised some concerns around software validation, cybersecurity, and usability.

Testing Volume vs. Feasibility: FDA guidance on oxygen therapy devices required extensive electrical safety, EMC, and biocompatibility testing. The startup needed to sequence these efficiently within a limited allocation.

Investor & Manufacturing Timelines: The founders needed regulatory clarity to communicate realistic milestones to investors and contract manufacturers.

Elexes' Approach

Focus Area	Elexes' Targeted Support
Regulatory Pathway Determination	Conducted a comparative regulatory analysis of ventilators, CPAPs, and oxygen conservers to identify the most suitable predicate family. Positioned the device under Class II (510(k)) rather than De Novo, saving months in review time.
Device Definition & Labeling	Collaborated with the engineering team to refine the device description, flow diagrams, and intended use. Crafted labeling and IFU language that clearly differentiated the product's training function from life-support systems.
Risk Management (ISO 14971)	Created a detailed hazard analysis focusing on oxygen concentration variance, flow interruption, and user misuse. Linked mitigations to performance testing and alarm functions.
Testing Strategy & Prioritization	Developed a staged testing roadmap: Bench and flow accuracy verification Biocompatibility of mask/tubing (ISO 10993) Electrical and EMC testing (IEC 60601-1/-1-2) Usability validation (IEC 62366). This sequencing minimized rework and controlled cost.
Software Validation Plan	Designed a validation protocol aligned with the FDA's General Principles of Software Validation and IEC 62304. Addressed cybersecurity controls for connected components.
Pre-Sub Development & FDA Interaction	Prepared a complete Pre-Sub package, including draft device description, risk files, and testing plan. Formulated FDA questions on pathway, testing depth, and software documentation. Managed FDA correspondence through written feedback.
510(k) Preparation & Submission	Integrated FDA feedback into the final submission, addressed all Additional Information (AI) requests, and coordinated responses until clearance.

Results & Impact

- FDA confirmed Class II (510(k)) classification and accepted the proposed testing plan without requiring additional bench or clinical studies.
- 510(k) clearance obtained on first submission, with no major deficiencies.
- Optimized testing roadmap saved approximately 4 months and >$80,000 in redundant validation.
- Early FDA feedback enabled the engineering team to finalize prototype design and labeling with confidence.
- The client successfully presented an FDA-aligned development plan during its investor round, facilitating funding.

Broader Relevance

- This project exemplifies the regulatory and technical complexities faced by manufacturers of oxygen delivery, ventilator, and respiratory training systems that incorporate software-driven control and patient monitoring.

- Elexes' structured approach, combining risk-based testing, phased FDA interaction, and documentation excellence, can be directly leveraged for:
- CPAP and ventilator systems introducing adaptive pressure or flow control.

- Rehabilitation or cardiopulmonary training devices combining mechanical and physiological feedback.

- Smart respiratory or metabolic health platforms integrating SpO_2 and sensor data analytics.

Why It Matters

Elexes' deep familiarity with FDA Pre-Sub and 510(k) processes for respiratory and oxygen therapy devices allows innovators to move confidently from concept to clearance.

By translating complex engineering into FDA-aligned documentation, sequencing testing efficiently, and maintaining transparent communication with reviewers, Elexes consistently enables faster, safer, and more cost-effective market access for breakthrough respiratory technologies.