CASE STUDY

Accelerated 510(k) Clearance for Hemodialysis-Related Class II Device with Robust Microbial Safeguards

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Background

- A U.S. based medtech innovator engaged Elexes to support FDA 510(k) clearance for a Class II device intended for use in hemodialysis water distribution systems.

- This accessory was critical for infection control and was required to meet stringent microbial risk mitigation standards, particularly relevant due to its contact with water pathways and potential exposure to pathogens.

Regulatory Challenge

- The device's primary challenge was demonstrating safety and effectiveness related to microbial control while aligning with modern FDA expectations on eSTAR submission formatting, risk management, and performance testing.

- Time was also a constraint: the client needed clearance within a 5–6-month window to meet investor and distribution deadlines.

Elexes' regulatory strategy

Elexes developed a comprehensive end-to-end strategy including:

- **Pre-sub guidance:** Advised against unnecessary pre-sub due to strong predicate similarity and clear testing framework.
- **Predicate analysis:** Mapped a direct match with a cleared Class II dialysis device and adjusted intended use and technological characteristics accordingly.
- **eSTAR-ready dossier preparation:** Structured submission for FDA's electronic Review Template (eSTAR) compliance from the outset.
- **Infection control measures:** Leveraged ASTM E2315 and ISO 11737-based microbial efficacy testing to validate biofilm prevention and filtration efficiency.
- **Risk management file:** Constructed a fully traceable risk file per ISO 14971, linking risk controls to verification and validation (V&V) outputs.
- **IEC/ISO standards:** Integrated testing to support IEC 60601-1 (if applicable), biocompatibility (ISO 10993), and cleanability guidelines.
- **Clinical justification:** Provided a clinical rationale showing that bench testing plus literature sufficed, avoiding costly clinical trials.
- **Performance testing:** Included pressure endurance, flow rate verification, and backflow prevention, benchmarked against ISO 26782.

Communications with FDA

- **510(k) submission:** Delivered in eSTAR format with a quality technical dossier.
- **RTA response:** Received within 12 days of submission; responded in <5 business days.
- **AI (additional information) letter:** Addressed with zero deficiency repeats, using pre-prepared data packs aligned with FDA reviewer guidance.

Results

- **510(k) clearance time:** 138 calendar days from submission to clearance
- **Zero repeat cycles:** No second-round AI or RTA issues
- **Market readiness:** Device moved to production within 2 weeks post-clearance

Significant impact

The successful methodology has since been applied to similar point-of-use water treatment devices, including anti-Legionella filters and sterile water plumbing accessories. Our infection control and microbial validation experience is highly adaptable across various water-interfacing medical devices.

Why Elexes?

- Cross-functional regulatory and technical experts
- Proven track record with microbial risk-driven devices
- Speed-to-clearance without compromising documentation integrity
- Fluent in eSTAR, ISO standards, and FDA expectations

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