

Elegant by Design: Simplifying a Safety-Critical System into an Acquisition-Worthy Product

The Project

A startup sought to bring a critical life support device to market but faced complex integration challenges and an aggressive timeline. Forj Medical applied cross-functional expertise to transform separate systems into a commercially viable, portable device that helped the startup achieve FDA clearance and subsequent acquisition.

The Challenge

Multiple systems had to be consolidated into a lightweight, battery-powered, waterproof device that met aerospace standards for use in helicopters and planes. The compact form factor required thermal management and redundant architecture to ensure reliability in demanding environments. It was one of the first devices subject to the 2022 FDA Draft Cyber Guidance, adding a layer of complexity, and a pandemic-driven supply chain crisis threatened to derail the project when speed was critical. The startup's goal of acquisition meant not only solving technical challenges, but also proving scalable manufacturability while meeting future production cost targets.

The Solution

Forj Medical optimized the layout across eight printed circuit board assemblies (PCBAs) within a ruggedized, sealed, IP33-rated chassis. We developed custom fins to dissipate heat and implemented fail-safe architecture, including a redundant power supply and field-programmable gate array (FPGA) motor control algorithms. Our software engineers designed a language-agnostic UX, conducted penetration and unit testing, and developed documentation for cybersecurity compliance. We eliminated supply chain issues by designing in and procuring available components, secured 510(k) clearance, and met aerospace requirements. Through close client collaboration, we transformed cumbersome systems into a single, elegant device weighing under 20 pounds, applying Design for Manufacturing (DFM) principles to scale from proof of concept to commercial production in less than two years – on schedule and on budget – ultimately helping our client achieve acquisition by a major medical device OEM.

