TripleRing

IVD Platform Refresh

Client
Fortune 500 IVD Company

Practice Areas
TechBio & Life Sciences

Core Disciplines
Software Engineering
Molecular & Cell Biology
Mechanical Engineering
Transfer to Manufacture
Electrical Engineering
Embedded Systems

Challenge

A Fortune 500 diagnostics manufacturer faced obsolescence of critical hardware components — including single-board computers and microcontrollers — within an existing FDA-cleared diagnostic platform, compounded by the absence of original firmware source code and diminished institutional knowledge. The refreshed system needed to restore full functionality while maintaining regulatory equivalency with the original device to qualify for a Special 510(k) submission — leaving no margin for unintended performance deviation.

Solution

Triple Ring implemented a structured modernization strategy combining reverse engineering, hardware redesign, and software migration to preserve functional equivalency while introducing modern, supportable components. Legacy hardware and software architectures were reverse engineered to reconstruct lost system knowledge, obsolete electronic components were replaced with supported alternatives, and new firmware was developed compatible with legacy system functions. Updated industrial design elements were integrated to support usability and manufacturability, with a comprehensive regulatory submission package developed in parallel throughout.

Client Impact

- Delivered a fully refreshed IVD platform supported by a complete regulatory submission package demonstrating Special 510(k) equivalency
- Restored long-term hardware and software sustainability while maintaining full functional continuity with the original FDA-cleared device
- Integrated seamlessly into existing manufacturing workflows, enabling uninterrupted production at maintained cost targets
- Positioned the platform for continued market competitiveness with a modern, maintainable architecture and clear regulatory pathway

Find more case studies on our website: