



OVERVIEW

Blue Goat Cyber - Company Overview

Medical Device Cybersecurity · FDA-Aligned · Built by Operators

Blue Goat Cyber is a specialist medical device cybersecurity firm. We help MedTech manufacturers clear FDA review, secure connected devices end-to-end, and build the kind of post-market program that holds up to scrutiny.

What we do

- FDA premarket cybersecurity submissions (510(k), De Novo, PMA).
- Medical device penetration testing - firmware, app, cloud, RF.
- Threat modeling aligned to MITRE/MDIC and FDA expectations.
- FDA-compliant SBOM generation and lifecycle management.
- Post-market vulnerability management and Section 524B compliance.

Why MedTech leaders choose us

- Senior practitioners on every engagement - no junior hand-offs.
- Submission-ready deliverables, not raw scan output.
- Direct experience responding to FDA AI requests.
- Fixed-scope pricing tied to your submission milestones.

Recent recognition

- Medical Device Cybersecurity Company of the Year, 2025.
- Featured at AMDM, DeviceTalks, and HIMSS programs.
- Trusted by Class II and Class III device manufacturers across the US and EU.

Ready to talk through your roadmap?

[Book a Strategy Session →](#)