BLUE GOAT CYBER™

FDA-ready cybersecurity for connected medical devices

COMPANY OVERVIEW · 2026

STANDARDS WE BUILD & DELIVER TO

FDA 524B | AAMI SW96 | AAMI TIR57/97 | IEC 81001-5-1 | ISO 14971

SDVOSB · VETERAN-OWNED · EST. 2022

WHY WE EXIST

Founder **Christian Espinosa**, a U.S. Air Force Academy graduate and veteran, built Alpine Security (acquired by CISO Global, 2020), then survived a serious health scare on the receiving side of medical technology. That experience reframed the work as **patient safety with a pulse**. Blue Goat Cyber was founded in 2022 with a deliberately narrow charter: **medical devices only, FDA submissions only, senior practitioners only.**

Secure by design. Cleared by the FDA.

A specialist medical device cybersecurity firm delivering end-to-end Secure Product Development Framework support mapped 1:1 to FDA Section 524B and the Feb 3, 2026 premarket guidance: threat modeling, SBOM/VEX, penetration testing, architecture views, and the complete eSTAR-ready submission package. Veteran-owned and US-based: no offshoring, no first-year analysts learning on your submission, no surprise change orders.

250+ FDA SUBMISSIONS SUPPORTED

Zero CYBER-RELATED CLEARANCE DENIALS

48hr MEDIAN DEFICIENCY RESPONSE

11yrs MEDTECH CYBER ROOTS, SINCE 2015

WHAT WE DELIVER

FDA Premarket Package FLAGSHIP

End-to-end Section 524B evidence as a single fixed-fee package: threat model, SBOM, security risk management, architecture views, manual pen testing, labeling, and the full submission. 6–8 weeks, proposal in 24 hours.

Penetration Testing

Hardware, firmware, mobile/cloud, wireless, and AI/ML attack-surface testing, scoped from the device threat model. Reports drafted for CDRH reviewers.

Threat Modeling (STRIDE / Patient Safety)

STRIDE and patient-safety threat models with explicit links to risk management (ISO 14971 / AAMI TIR57) and design controls.

SBOM, VEX & Vulnerability Mgmt

CycloneDX/SPDX generation, VEX statements, and KEV monitoring, with a postmarket workflow that keeps your SBOM defensible long after clearance.

FDA Deficiency Response

Surge support for FDA cybersecurity Additional Information letters. Median 48-hour first-pass response; no client has failed a second round to date.

Postmarket Cybersecurity

Coordinated vulnerability disclosure, incident playbooks, and continuous SBOM/VEX and KEV monitoring through GoatWatch, our surveillance platform.

WHERE YOU FIT IN: FIVE LIFECYCLE STAGES, CONCEPT TO POSTMARKET

01 · 2–7 YRS OUT	02 · ~9 MO OUT	03 · SUBMISSION	04 · AI LETTER	05 · IN FIELD
Concept & Design	**Premarket**	**FDA Submission**	**FDA Response**	**Postmarket**
SPDF setup, early threat model, SBOM strategy, 524B plan.	Pen test, threat model, SBOM, architecture views.	Full 524B package, eSTAR-ready. 6–8 wks, fixed fee.	Deficiency rewrite, reviewer Q&A. 48-hr first pass.	CVD, GoatWatch monitoring, incident playbooks.

WHY TEAMS HIRE US

- **Fixed-fee, no T&M:** scoped, quoted, and signed before kickoff.
- **24-hour proposal SLA:** scoping call to fixed-fee proposal in one business day.
- **Senior-led delivery:** every phase run by a principal who has personally cleared FDA submissions.
- **Submission-ready artifacts:** formatted to eSTAR structure, drop in as-is.
- **Standards-mapped:** every deliverable traces to FDA 524B, AAMI SW96, TIR57/97, IEC 81001-5-1, and ISO 14971.

PROOF & RECOGNITION

- ★ **2026** MedTech World N. America, Cybersecurity Partner of the Year
- ★ **2026** Medical Tech Outlook, Solution of the Year (cover)
- ★ **2025** MedTech World Malta, Service Provider Excellence
- ★ **2025** Healthcare Business Review, Company of the Year

> *"Their timeline exceeded expectations, and their report helped us achieve FDA clearance without any additional questions."*
>
> **Anna Norman, VP of Product, InfoBionic.ai**

Let's talk before your next submission.

Principal-led 30-minute scoping call · fixed-fee proposal within 24 hours.

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SCAN TO BOOK A DISCOVERY CALL