



CHECKLIST

FDA Cyber Readiness Checklist

10-minute pre-submission gut check · Aligned to FDA 2026 final guidance & Section 524B

Use this checklist before locking your 510(k), De Novo, or PMA submission. If you cannot tick every box, your reviewer will find the gap first. Each item maps to a question we routinely see in FDA Additional Information (AI) requests.

1 · Secure Product Development Framework (SPDF)

- SPDF narrative is written in product-specific language - no boilerplate.
- Threat model is dated, versioned, and signed off by a named owner.
- Security risk management file traces threats → controls → verification evidence.
- Design inputs include cybersecurity requirements with measurable acceptance criteria.
- Verification & validation evidence is mapped to each cybersecurity requirement.

2 · Software Bill of Materials (SBOM)

- SBOM is machine-readable (SPDX or CycloneDX) - not a PDF table.
- Every component lists supplier, name, version, and known-vulnerability status.
- End-of-support / end-of-life dates documented for every third-party component.
- Process described for refreshing the SBOM at each release and post-market.

3 · Postmarket Vulnerability & Patch Plan

- Coordinated vulnerability disclosure (CVD) policy is published and reachable.
- Patch cadence and emergency-patch SLA defined in writing.
- Customer notification process documented with sample comms.
- Internal monitoring sources listed (NVD, ICS-CERT, vendor feeds).

4 · Architecture & Controls Evidence

- Authentication, authorization, and audit logging described per interface.
- Cryptographic controls list algorithm, key length, and key-management approach.
- Update mechanism includes signature verification and rollback protection.
- Network interfaces enumerated with rationale for each open port/service.



| 5 · Labeling & Customer Documentation

- Cybersecurity section of labeling lists assumptions, residual risk, and customer responsibilities.
- MDS2 form (or equivalent) is current and matches the as-built device.
- Operator instructions cover incident reporting and patching workflow.

Ready to talk through your roadmap?

[Book a Strategy Session →](#)

This checklist is provided as guidance only and does not constitute legal or regulatory advice. Submission requirements vary by device classification and FDA review division.