DATASHEET

Finite State's Next Generation Platform for Medical Device Manufacturers

Delivering high-quality, secure, and innovative products on time is crucial for medical device manufacturers. Traditional AppSec tools alone aren't enough to provide the SBOM documentation needed to comply with FDA cybersecurity guidance. Submissions relying on this evidence alone could result in a "Refuse to Accept" issuance by the FDA, delay product launches, and incur large cost outlays.

Since many binary components are added at the final software build step, there's often no access to their source code, which means AppSec tools won't detect and report on them. The FDA's final guidance on cybersecurity states, "(3) provide to the Secretary a software bill of materials, including commercial, open-source, and off-the-shelf software components." **You need a complete SBOM that includes all of the software components within your connected product.**

Finite State solves this problem for medical device manufacturers with **easy-to-generate and complete SBOMs that deliver in-depth analysis and visibility into all commercial, open-source, and off-the shelf software components, including binary operating systems and files.** Shorten the time to market with easy, automated documentation and generation to provide proof of security and testing to customers and regulators.

Security Tooling Made for Medical Device Manufacturers

Finite State has the tools to help you prepare your FDA premarket submissions. We have worked to clarify the FDA's cybersecurity guidance for premarket submissions, so you can feel assured that we can effectively support your submission process. Finite State offers:

- An insights dashboard so you can see all your product submissions compiled through Finite State
- A prioritized list of vulnerabilities that your team should triage
- Easy download of all your evidence documentation, like submission-friendly SBOMs in JSON format, Vulnerability Disclosure Reports, and any uploaded reports and results from penetration tests, threat modeling, or other third-party tools

Finite State Next Generation Platform Capabilities

End-to-End SBOM Solution

Finite State's end-to-end SBOM solution delivers critical capabilities like SBOM generation, import, enrichment, and distribution. Our binary SCA capability can create detailed SBOMs from uploaded binaries, including open-source and proprietary components. Import SBOMs from other sources for an even more comprehensive picture of your portfolio, which we then enrich for you through nightly updates to our vulnerability intelligence. When it's time to submit documentation, we offer options for export into CycloneDX, SPDX, and VEX/VDR formats.

Binary Analysis

Finite State's industry-leading binary analysis is a cornerstone of our offering, leveraging binary SCA and SAST capabilities to decompose binary images into their subcomponents (like embedded software, drivers, and kernels); examine decompiled source code for unsafe function calls; and analyze subcomponents to identify weaknesses like insecure configurations, hard-coded credentials, cryptographic materials, and more.

Unified Visibility and Risk Management

Streamline your risk management efforts with Finite State's advanced application security posture management capabilities: import and parse documents from over 150 other AppSec scanning tools; integrate upload and scanning functionality into your workflows with our SDK, APIs, and CI/CD integrations; leverage our intuitive risk scoring algorithm for cross-portfolio risk analysis and prioritization; and a suite of dashboards and reports to track progress against product security goals.

Flexible Deployment Models

We know our customers have a range of needs and priorities for securing their environments, and we offer flexible options to support these needs. We proudly offer SaaS, hybrid cloud, and on-premise installations.

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