

FDA Issues Long-Awaited Premarket Guidance

Industry Leading Vigilant Ops InSight Platform Supports Cybersecurity Requirements

PITTSBURGH, PA, UNITED STATES, September 29, 2023 /EINPresswire.com/ -- The United States Food and Drug Administration (US FDA) issued the [final version of their guidance document](#)

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Ken Zalevsky

titled “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions – Guidance for Industry and Food and Drug Administration Staff” on September 27, 2023. This important guidance document has been revised multiple times over the last several years, starting with the initial release in 2014 through draft releases in both 2018 and 2022.

“Medical device manufacturers have been eagerly awaiting this guidance to gain clarity and understanding of FDA requirements. These 48 pages provide more detailed descriptions and clarify FDA’s expectations, with respect to

cybersecurity requirements across the device lifecycle”, said Ken Zalevsky, CEO at Vigilant Ops. “In addition, our platform was designed to support these exact requirements, and our clients have already been successfully complying with requests from global authorities, such as FDA.”

A few specific requirements (for a more detailed summary of the guidance, click [here](#)):

- Software Bill of Materials (SBOM) as per section 524B(b)(3) of the FD&C Act
- Vulnerability monitoring - “As part of the premarket submission, manufacturers should also identify all known vulnerabilities associated with the device and the software components”
- Metrics required with submissions and annual PMA reports

Given the rash of ransomware attacks in healthcare, and the very real threat to patient safety, the need to strengthen the cybersecurity profile of medical devices has never been greater. With legislative authority to enforce these premarket requirements, as per the recent modifications to the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is moving quickly to encourage device makers to adopt the recommendations in this guidance document.

Manufacturers have had the opportunity to begin planning and implementing the enclosed recommendations in order to comply with the guidance. Of course, this is just one step along the evolving path to make healthcare safer and more secure for everyone. The medical device cybersecurity ecosystem will continue to change and evolve, requiring stakeholders to

continuously adapt. The granting of legislative authority to FDA to enforce cybersecurity compliance communicates the need for action on the part of industry stakeholders. However, while complying with the law might be the immediate concern, cybersecurity is not just a “check the box” activity. The breadth and depth to which organizations are impacted by cybersecurity makes it a strategic imperative and limiting one’s view to tactical implementation is not recommended.

About Vigilant Ops

Founded in 2019, Vigilant Ops is an innovator in the medical device cybersecurity industry. Led by medical device cybersecurity experts, Vigilant Ops provides medical device manufacturers and hospitals with unprecedented insight into device risk profiles, enabling proactive management of threats, before they impact the quality of patient care. “We founded Vigilant Ops with the healthcare industry in mind and our solution is designed to support the medical device manufacturers to comply with current and future requirements,” said Zalevsky. “InSight is more than a point solution and fosters additional collaboration by connecting technology producers with technology consumers.” By collecting and curating massive amounts of data, the platform can quickly and easily generate required cybersecurity metrics and cybersecurity management plans that can be provided as part of submissions, annual reports, or shared with consumers.

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