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What You Need to Know

to Start Implementing the FDA's New Medical Device Security Requirements

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Setting the Stage — A Brief History

- On December 29, 2022, the Consolidated Appropriations Act, 2023 ("Omnibus") was signed into law:
  - Section 3305 - Ensuring Cybersecurity of Medical Devices

The Omnibus Bill gives statutory authority to the FDA in regulating cybersecurity in medical devices

- Enforcement Capabilities

All devices that contain software, are able to connect to the internet, or may be vulnerable to cybersecurity threats must comply with these requirements

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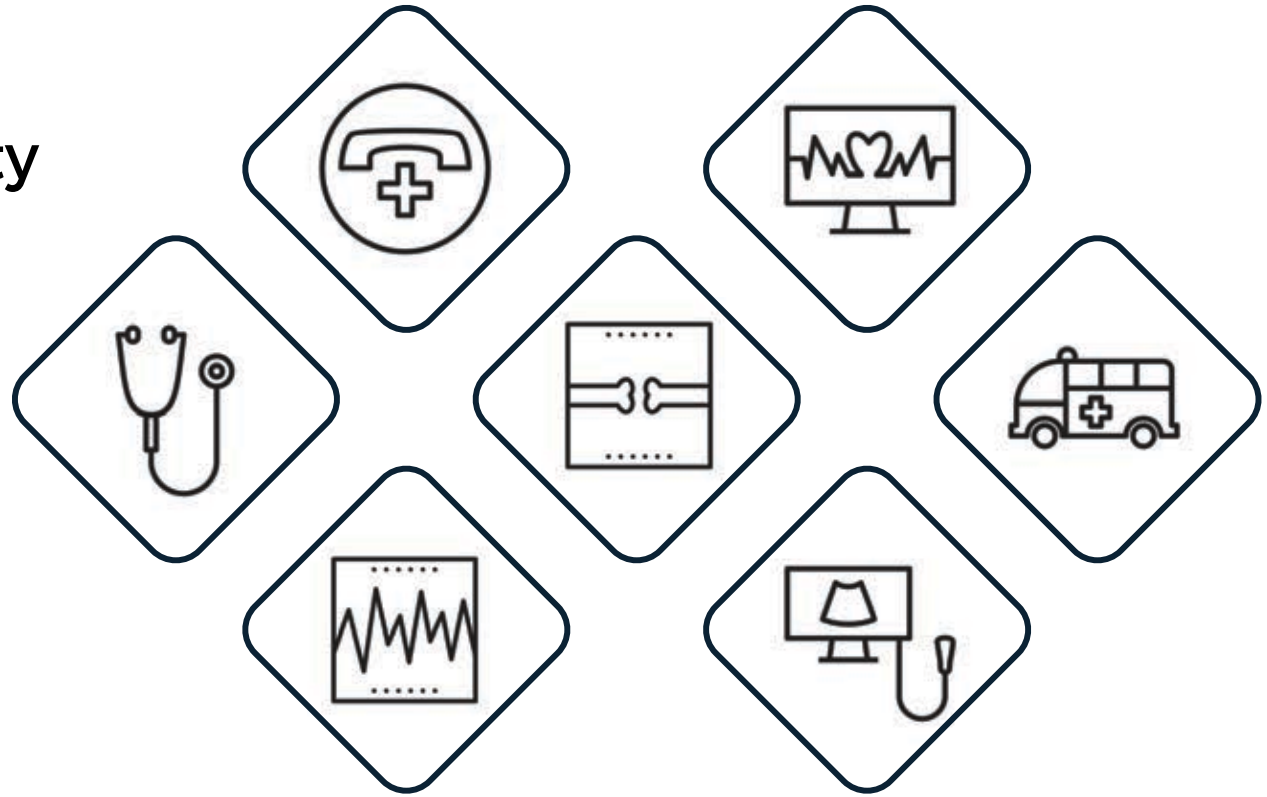
Nuances of Medical Device Security

- Development (SDLC)
- Device Control / Connectivity
- Shadow IT
- Connected Devices
- Data Protection
- Encryption / Device Communication
- Patient safety…



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The Omnibus Rule

1. FDA now has dedicated funding for enforcement ($5M)
2. The Omnibus finalized guidance on:
    - Reasonably updated patch / update cycles
    - Medical devices are moving toward secure by design & secure lifecycle concepts
3. The latest update gives a definition of a “cyber device”
    - Includes software validated, installed, or authorized by the sponsor, indicating its integral role in device functionality.
    - Must possess the ability to connect to the internet.
    - Encompasses any technological characteristics that have been validated, installed, or authorized by the sponsor, which could potentially be susceptible to cybersecurity threats.

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The Omnibus Rule (Cont'd)

- "…a plan to monitor, identify, and address, as appropriate, in a reasonable time, postmarket cybersecurity vulnerabilities and exploits, including coordinated vulnerability disclosure and related procedures."
- "…design, develop, and maintain processes and procedures to provide a reasonable assurance that the device and related systems are cybersecure, and make available postmarket updates and patches to the device."
- "…provide a software bill of materials, including commercial, open-source, and off-the-shelf software components."
- "…comply with such other requirements through regulation to demonstrate reasonable assurance that the device and related systems are cybersecure."

Requirements of Submitting Plan to FDA

- Develop a strategy for monitoring, identifying, and addressing cybersecurity vulnerabilities and potential exploits
- Plan for addressing vulnerability disclosures and establishing incident response protocols
- Plan for routine post-market updates and patches

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Breach Notification Guidelines and Incident Reporting

- Report certain cyber incidents to the Cybersecurity and Infrastructure Security Agency (CISA) within 72 hours after a substantial incident
- Report ransomware payments within 24 hours

Note!

These requirements won't go into effect until late 2024 or 2025 when the final rulemaking is expected.

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Key Takeaways

1. FDA now has dedicated funding
2. The Omnibus finalized guidance on:
    - Reasonable patch update cycles
    - Secure by design
3. Updated definition of a “cyber device”
    - Includes software validated, installed, or authorized by the sponsor, indicating its integral role in device functionality.
    - Must possess the ability to connect to the internet.
    - Encompasses any technological characteristics that have been validated, installed, or authorized by the sponsor, which could potentially be susceptible to cybersecurity threats.

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