# Medical Device Cybersecurity Fleet Management

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## Regulatory Frame

FDA's Section 524B (postmarket cybersecurity), FDA's premarket cybersecurity guidance, EU MDR cybersecurity provisions, and emerging IEC 81001-5-1 standardization establish medical-device cybersecurity requirements. SBOM submission, vulnerability management, and incident reporting are architecturally required.

Implementation-level compliance is OEM-by-OEM.

## Fleet-Health Substrate

Each medical-device contributes continuous credentialed health observations. SBOM attestation, PUF challenge-response, governance-chain integrity, and cross-fleet composite assessment all integrate.

FDA participates as credentialed regulatory observer; cross-OEM operations admit through declared federation.

## Medical Cybersecurity Trajectory

FDA enforcement maturation, EU MDR cybersecurity enforcement, emerging international medical-device cybersecurity harmonization all benefit from architectural fleet-health substrate.