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In The News

Betsy Hodge Says Medical Device Makers Should Closely Review FDA's Draft AI Guidance

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The Food and Drug Administration (FDA) released for public comment this week non-binding draft guidance for artificial intelligence-enabled medical devices. Healthcare and Data Privacy Partner Betsy Hodge tells *Healthcare Info Security* that, while not binding, the document provides device makers a clear outline of the FDA's current position, particularly regarding cybersecurity.

"It is imperative for AI-enabled medical device makers to consider cybersecurity issues in the life cycle of their products because cybersecurity threats can compromise the safety and/or effectiveness of a device, potentially resulting in harm to patients," Hodge told the publication.

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