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Software as a Medical Device (SAMD): Clinical Evaluation Guidance for Industry and Food and Drug Administration Staff Document issued on December 8, 2017. The draft of this...



Clinical Decision Support Software

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US-FDA-Artificial-Intelligence-and-Machine-Learning-Proposed Framework

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pg. 1 www.fda.gov pg. 2 www.fda.gov Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD...







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