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ARTICLE

The Patent Protection Conundrum Facing Producers of AI-enabled Software as Medical Devices

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Earlier this year, the FDA released a discussion paper entitled Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Devices (SaMD), which proposes a regulatory framework for governing medical devices that incorporate artificial intelligence.

In the discussion paper, the FDA recognized that AI-based medical devices may have potentially significant benefits. The FDA highlighted AI's "ability to learn from real-world use and experience, and its capability to improve its performance," for example as the AI tools learn from new data over time. The FDA also predicted that "AI/ML-based SaMD will deliver safe and effective software functionality that improves the quality of care that patients receive."

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