Insights: Publications

A First Look at the FDA's Proposed Regulatory Framework for Modifications to AI-Based Software as a Medical Device (SaMD): IP Review and Strategy Guide

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Software has become an integral part of our society. Virtually every aspect of life could incorporate software at some level (e.g., smart toothbrushes, digital currency, app-controlled thermostats, etc.). When applied to health, mobile devices already track steps and heart rate and will call 911 if the wearer is immobile after a hard fall. Products within the medical field from hospitals to pharmaceutical and medical device companies are being improved through software to give patients more knowledge and control over their diagnosis and treatment. It is when software is intended to diagnose or treat that software qualifies as a medical device in and of itself and therefore necessitates its own approval from the Food and Drug Administration (FDA).