Artificial Intelligence: The Game Changer of Medtech

What's the regulatory landscape for AI-enabled devices?

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The year 2018 has seen a good influx of innovative medical devices. Artificial intelligence (AI) serves as a critical component in most of these novel devices.

FDA has defined artificial intelligence as:

"A device or a product that can imitate intelligent behavior or mimics human learning and reasoning. Artificial Intelligence includes machine learning, neural networks, and natural language processing. Some terms used to describe artificial intelligence include: computer-aided detection/diagnosis, statistical learning, deep learning, or smart algorithms."

While AI has long been relegated to perform tasks like managing medical records and medication management, it has now become an intelligent contributor wherein it can interpret the results on its own, without the need of a physician or a caregiver. This has drastically reduced the consultation time for physicians. However, with no existing predicates in the market, it has been a tough task for