Hogan Lovells

Medical Device Artificial Intelligence

From smartphones to self-driving cars, artificial intelligence (AI) influences nearly every aspect of modern life. Health care is no exception. Use of artificial intelligence systems promises better health care management for patients and faster, more accurate diagnoses for doctors. Companies pursuing AI technologies must realize that while the health care industry is embracing this technology, the regulatory landscape is still finding its footing. That's where we can help.

Hogan Lovells has been at the forefront of medical device AI regulation. We have advised our clients on the clearance or approval of numerous medical devices that incorporate artificial intelligence algorithms. From analysis of medical imaging such as echocardiograms, computed tomography (CT), endoscopy, and skin photographs, to tissue histology and physiological data, such as electrocardiograms (ECG), these technologies have demonstrated enormous potential for health care. They are designed to screen for diseases, classify malignancies, and provide personalized treatment recommendations, among other things, often sooner than has been possible using traditional technologies.

At the same time, these products raise unique regulatory questions due to their iterative and potentially self-updating nature, which is incongruent with historical regulatory approaches. The use of machine or deep learning offers the opportunity for

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Practices

Medical Device and Technology Regulatory

continual optimization of an algorithm as new training data becomes available; whereas traditional regulatory approaches have focused on frozen algorithms that require new clearance or approval if changes are made postmarket.

Representative experience

Developed an innovative strategy for interacting with FDA allowing Viz.ai to gain a quick De Novo clearance for a novel Computer-Aided Triage and Notification Platform to identify Large Vessel Occlusion strokes in CTA imaging.

Successfully assisted IDx LLC to achieve De Novo reclassification from the FDA for the groundbreaking AI-based device IDx-DR, which autonomously analyzes images of the retina for signs of diabetic retinopathy.

Assisted CSD Labs in obtaining 510(k) clearance of eMurmur, an innovative, AI-based murmur detection software.

Advised Bay Labs in seeking 510(k) clearance for its EchoMD AutoEF software, which applies machine learning algorithms to process echocardiography images in order to calculate left ventricular ejection fraction.

Assisted numerous clients with novel medical devices featuring AI and machine learning algorithms in developing and gaining FDA alignment on creative regulatory strategies to bring these innovative products to market in the U.S.

Latest thinking and events

News

Panelists discuss present & future reimbursement mechanisms for AI health care products

News

FDA spells out electromagnetic compatibility info needed in medical device premarket submissions

News

Emerging AI issues affecting EU, UK life sciences firms

News

Evolution of FDA regulation of AI-based technology

Insights

Senate proposes greater FDA oversight of Lab Developed Tests

News

Building a resilient tech strategy: The future of tech