

## 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 continual optimization of an algorithm as new training data becomes available; whereas traditional regulatory

### Contacts

John J. Smith, M.D., J.D.,  
Washington, D.C.

Kelliann H. Payne,  
Philadelphia

Dr. Jörg Schickert,  
Munich

Cybil Roehrenbeck,  
Washington, D.C.

---

### Practices

Medical Device and  
Technology 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

FDA warns over use of robotically-assisted surgical devices

### News

The journey has just begun: China passes its Personal Information Protection Law

### News

Hogan Lovells responds to the European Commission's consultation on the AI Regulation

### News

After a long and winding road, FDA finalizes much-debated "intended use" rule

### News

Shenzhen finalizes the local data regulation

News

A new era for Australian online safety regulation