



FDA Permits Marketing of First Autonomous Artificial Intelligence-Based Medical Device

On April 11, 2018, the U.S. Food and Drug Administration ("FDA") permitted marketing of the first device to use artificial intelligence ("AI") autonomously to detect a medical condition. The device, called IDx-DR, utilizes an AI algorithm to screen for diabetic retinopathy. The device is unique in that its results do not require additional review by a specialized clinician, which allows the test to be performed in a primary care setting.

To use IDx-DR, images of the patient's eyes are first taken with a retinal camera and uploaded onto a cloud server where the device is installed. Then, within minutes, IDx-DR provides the doctor with results, indicating whether it detects more than mild diabetic retinopathy, in which case the patient should see an eye specialist, or that the screening was negative and the patient should be tested again in a year.

Like many devices in the digital space, IDx-DR was reviewed through FDA's De Novo premarket review pathway, which is used for novel devices that present a low-to-moderate-risk to patients. Additionally, IDx-DR was granted Breakthrough Device designation, which expedites the review of medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

FDA has consistently stated its intention to be flexible with developers of digital health products whose software and devices often do not fall neatly into long-established product types. The successful utilization of the De Novo and Breakthrough Device programs for IDx-DR should encourage innovation by providing an FDA roadmap for other companies developing software and AI-based medical devices.

CONTACTS



Maureen Bennett
Boston / San Francisco



Alexis S. Gilroy
Washington



Ian M. Pearson
Washington

SUBSCRIBE

SUBSCRIBE TO RSS



Jones Day is a global law firm with more than 2,500 lawyers on five continents. We are One Firm WorldwideSM.

Disclaimer: Jones Day's publications should not be construed as legal advice on any specific facts or circumstances. The contents are intended for general information purposes only and may not be quoted or referred to in any other publication or proceeding without the prior written consent of the Firm, to be given or withheld at our discretion. To request reprint permission for any of our publications, please use our "Contact Us" form, which can be found on our website at www.jonesday.com. The mailing of this publication is not intended to create, and receipt of it does not constitute, an attorney-client relationship. The views set forth herein are the personal views of the authors and do not necessarily reflect those of the Firm.