



For Immediate Release

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FDA to expedite review of IDx-DR, a breakthrough AI diagnostic system

(Iowa City, Iowa) January 22, 2018 – [IDx](#), a privately held AI diagnostics company, announced today that it has filed its De Novo submission to the FDA for IDx-DR, an AI-based system for the autonomous detection of diabetic retinopathy — a leading cause of blindness.

The FDA has granted IDx-DR with a “Breakthrough Device” designation, which means the submission will receive expedited review. The [Breakthrough Devices Program](#) is reserved for breakthrough technologies that “provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases.”

If cleared by the FDA, IDx-DR is expected to become the first-of-its-kind autonomous, AI-based diagnostic system intended for use in the front lines of healthcare.

“The FDA’s designation of IDx-DR as a ‘breakthrough device’ confirms what we have believed for a long time,” said [Dr. Michael Abràmoff](#), founder and president of IDx. “The healthcare system desperately needs a more efficient and cost-effective way to detect diabetic retinopathy. Too many patients go blind needlessly because they aren’t diagnosed in time.”

As a practicing retina specialist at the University of Iowa Hospitals & Clinics, Abràmoff knows firsthand how badly a solution like IDx-DR is needed. He sees many patients in his clinic who are already losing their vision because disease was caught too late.

[More than 30 million Americans have diabetes](#), and an estimated 24,000 lose vision each year from diabetic retinopathy, a complication of diabetes. If caught in its early stages, vision loss and blindness are almost entirely preventable, [yet only about half of people with diabetes get regular eye exams](#).

Abràmoff and his colleagues developed IDx-DR for use in the front lines of care, so that people with diabetes can have their eyes tested for diabetic retinopathy during routine office visits. IDx hopes its technology will make early disease detection more accessible and affordable for patients. Early detection and treatment of diabetic retinopathy has been shown to prevent vision loss according to the [American Academy of Ophthalmology](#).

IDx-DR’s proposed indications for use would enable health care providers to automatically detect more than mild diabetic retinopathy (mtmDR) in adults with diabetes who have not been previously diagnosed with diabetic retinopathy. The IDx-DR system, which analyzes images of the retina for signs of disease, provides instructions for follow-up care based on the level of disease detected. IDx-DR is investigational and not yet available for sale in the United States.

About IDx, LLC

IDx is an AI diagnostics company focused on developing clinically-aligned autonomous algorithms that identify disease in medical images. Its mission is to transform the quality, accessibility, and affordability of global healthcare through the automation of medical diagnosis and treatment.

IDx is a leader in automated medical image analysis. The company recently completed an FDA clinical trial for its first product, IDx-DR, an AI-based diagnostic system that detects diabetic retinopathy. A clearance determination is expected in 2018.

IDx also has algorithms in development for the detection of macular degeneration, glaucoma, Alzheimer's disease, cardiovascular disease, and stroke risk. The company was founded by world renowned retina specialists and has a strategic partnership with IBM Watson Health to distribute its products in the EU.

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