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FDA approves AI device for detecting diabetic retinopathy

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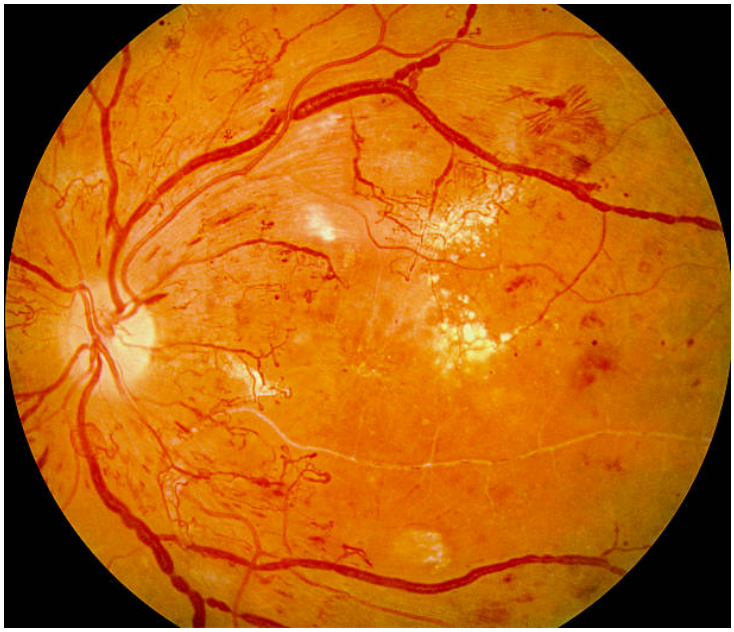
The device, called IDx-DR, is a software program that uses an AI algorithm to analyze images of the eye taken with a retinal camera called the Topcon NW400.



The U.S. Food and Drug Administration (FDA) has permitted marketing of the first medical device to use artificial intelligence (AI) to detect greater than a mild level of the eye disease diabetic retinopathy in adults who have diabetes.

The device, called IDx-DR, is a software program that uses an AI algorithm to analyze images of the eye taken with a retinal camera called the Topcon NW400. A doctor uploads the digital images of the patient's retinas to a cloud server on which IDx-DR software is installed. If the images are of sufficient quality, the software provides the doctor with one of two results: (1) more than mild diabetic retinopathy detected: refer to an eye care professional or (2) negative for more than mild diabetic retinopathy; rescreen in 12 months.

IDx-DR is the first device authorized for marketing that provides a screening decision without the need for a clinician to also interpret the image or results, which makes it usable by health care providers who may not normally be involved in eye care.