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USFDA approves AI software to detect diabetic retinopathy

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IDx-DR will be used to detect diabetic retinopathy, in which high levels of blood sugar lead to damage in the blood vessels of the retina and vision loss.



Singapore - Under its De Novo (no predicate product) review pathway, the FDA approves the first medical device in the U.S. that uses artificial intelligence (AI) to perform its designated function. The device, called IDx-DR, is a software program used to detect greater than a mild level of diabetic retinopathy.

IDX-DR employs an AI algorithm to analyze eye images taken with a retinal camera called the Topcon NW400. The physician uploads the digital images to a cloud server with the software and, if the images are of sufficient quality, receives one of two responses: "more than mild diabetic retinopathy detected: refer to an eye care professional" or "negative for more than mild diabetic retinopathy; rescreen in 12 months."

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IDX-DR is the first FDA-approved device that provides a screening decision without a supporting interpretation from a clinician which allows it to be used by healthcare providers who are not normally involved in eye care. It was developed by privately held IDx LLC.