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FDA to review framework for AI based medical devices

05 April 2019 | News

Statement from FDA Commissioner Scott Gottlieb, M.D. on steps toward a new, tailored review framework for artificial intelligence-based medical devices



FDA has announced steps to consider a new regulatory framework specifically tailored to promote the development of safe and effective medical devices that use advanced artificial intelligence algorithms.

Artificial intelligence algorithms are software that can learn from and act on data. These types of algorithms are already being used to aid in screening for diseases and to provide treatment recommendations.

Last year, the FDA authorized an artificial intelligence based device for detecting diabetic retinopathy, an eye disease that can cause vision loss. The agency also authorized a second artificial intelligence based device for alerting providers of a potential stroke in patients.

FDA is taking the first step towards developing a novel and tailored approach to help developers bring artificial intelligence devices to market by releasing a discussion paper.

Other steps in the future will include issuing draft guidance that will be informed by the input FDA receives. The approach will focus on the continually-evolving nature of these promising technologies. FDA plans to apply the current authorities in new ways to keep up with the rapid pace of innovation and ensure the safety of these devices.