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FDA Approves Marketing of Clinical Decision Support Software for Stroke Triage in Midst of Renewed Focus on Digital Health Applications

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The Food and Drug Administration (FDA) recently **approved** the Viz.AI Contact application, a type of clinical decision support software designed to analyze computed tomography (CT) results that may notify providers of a potential stroke in their patients. This approval may indicate broader acceptance of clinical decision support software utilizing artificial intelligence for purposes of triage. The Chief Executive Officer of the company, Dr. Chris Mani, **claimed** the approval was the “first example of applied artificial intelligence software that seeks to augment the diagnostic and treatment pathway of critically unwell stroke patients.”

The FDA approved the platform through the de novo premarket review pathway. This risk-based process is intended for novel devices that have not yet been classified by the FDA and for which there is no legally marketed predicate device. If the FDA classifies the device as Class I or Class II, then it may be used as a predicate device for other 510(k) submissions. The result of the approval, according to the agency's **press release**, is Viz.AI's platform can now be used to provide a pathway for other similar computer-aided triage software devices “with the same medical imaging intended use.”

The platform is a computer-aided triage software that utilizes deep learning artificial intelligence to assist providers with diagnosing suspected patient strokes. The program attaches to a CT scanner, and when it finds a suspected large vessel occlusion (LVO) stroke, the program sends a notification to a specialist's mobile device (though the image must still be viewed on a clinical workstation). To gain FDA approval, Viz.AI submitted results from a performance study with 300 patients. The study compared the system's ability to analyze CT images for suspected LVO strokes against two trained neuro-radiologists. The platform demonstrated a 90% sensitivity rate at identifying suspected LVOs and had a median time between the scan and notification of a provider of six minutes. Within the study, such automatic notifications saved 52 minutes on average in the majority of cases.

This decision comes at a time when the agency is paying increasing attention to digital health applications. The FDA Commissioner, Scott Gottlieb, **announced** the agency's intention in February to create a Center of Excellence on Digital Health and to “further reduce the time and cost of market entry of digital health technologies while assuring appropriate patient safeguards by relying on post-market collection of real-world data.” In December 2017, the FDA issued **draft guidance** on clinical and patient decision support software that detailed the agency's understanding of the 21st Century Cures Act amendment of the definition of device in the Food, Drug, and Cosmetic Act (FD&C) Act. The amendment eliminated specific software functions from the definition of device if they met all four of the following criteria:

1. *Not* intended to acquire, process, or analyze a medical image or signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;
2. Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);
3. Intended for the purpose of supporting or providing recommendations to a health care professional about the prevention, diagnosis, or treatment of a disease or condition; and
4. Intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents [such that the health care professional is not relying primarily on the system's recommendations].

In the guidance, the agency noted that software functions that *are* intended for the purposes of analyzing images remain devices “subject to FDA oversight.” Viz.AI’s platform would be an example of such a clinical decision support device since its purpose is to analyze the CT images and provide feedback to medical professionals based upon the results of the analysis. Some other FDA determinations for digital health applications with AI include Cognoa’s Class II diagnostic medical device designation for its AI software platform for behavioral health and the FDA’s Expedited Access Pathway (EAP) designation for MedyMatch Technology’s intracranial hemorrhage detection software using artificial intelligence.

**AHLA thanks the Health Information and Technology Practice Group for sharing this Alert with the Academic Medical Centers and Teaching Hospitals, Hospitals and Health Systems, Life Sciences, and Physician Organizations Practice Groups.*

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