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FDA Approves Software Application That Alerts Providers of Potential Stroke in Patients

Article By:

Svetlana Lyapustina, Ph.D.

On February 13, 2018 FDA approved a software application with clinical-decision support capability, in this case alerting providers of a potential stroke in patients. The system, "Viz.AI Contact," is developed by a US/Israeli company named Viz.ai, which uses artificial intelligence and machine deep learning for analyzing medical images. Earlier in January, this system also received a CE Mark from the European authorities.

Stroke is caused by an interrupted blood supply to the brain; for example, due to a blood vessel's rupture. Stroke is among leading causes of mortality and long-term disability in the U.S. and other countries. The Viz.AI Contact system analyzes brain computed tomography (CT) scans, identifies a suspected large vessel blockage, and sends a text notification to the health care specialist.

To gain regulatory approval, the company submitted results of a retrospective comparison between the decisions of the Viz.AI Contact system and those of two trained neuro-radiologists, based on an analysis of 300 CT scans. Real-world evidence and information from clinical trials were also used.

Viz.ai describes itself as a "Direct-to-Intervention healthcare company," and their just-approved system for stroke as their "landmark product." Their future plans are unclear at this point. In principle, however, similar applications seem plausible, as CT scans are ubiquitous in modern medicine. The CT technique uses X-rays to image internal organs and structures, to facilitate diagnoses from dental abscesses to metastatic cancers.

This recent approval aligns with FDA's previously stated goals of advancing digital health policies and encouraging innovation. Moreover, going forward, FDA plans to "further reduce the time and cost of market entry of digital health technologies," according to the 13-February Statement from FDA Commissioner Scott Gottlieb, MD.

For Viz.AI, the agency used a De Novo premarket review pathway, which is reserved for new types of medical devices that are considered low to moderate risk and have no legally marketed predicate device. Subsequent similar systems, however, may now use the more common FDA process ("510 (k)"), which relies on demonstrating substantial equivalence to a predicate device. This means that the next system operating on a similar principle (e.g., use of AI and triage software) for a similar purpose (e.g., analyzing computed tomography images) may obtain U.S. regulatory approval based

on comparisons to Viz.AI Contact rather than on results of clinical trials or other extensive studies. The De Novo summary provides further insights into the types of information that the agency may be requesting in support of demonstrating substantial equivalence for a similar system in future 510(k) submissions.

Svetlana Lyapustina, Ph.D. contributed to this post.

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