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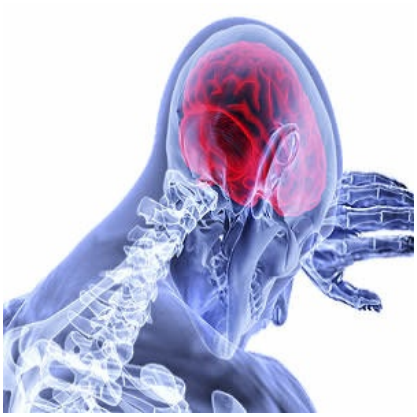
AI app for stroke detection approved by FDA



A new AI application that can analyse imaging data and alert physicians of a potential stroke in patients has received approval from the U.S. Food and Drug Administration (FDA). The Viz.AI Contact app uses an AI algorithm to analyse computed tomography (CT) scans and identify signs of a stroke in patients.

When the app identifies a potential blockage in the brain, it will notify a neurovascular specialist via smartphone or tablet, reducing the time to treatment.

“Strokes can cause serious and irreversible damage to patients. The software device could benefit patients by notifying a specialist earlier thereby decreasing the time to treatment. Faster treatment may lessen the extent or progression of a stroke,” said Robert Ochs, PhD, acting deputy director for radiological health, Office of In Vitro Diagnostics and Radiological Health in the FDA’s Center for Devices and Radiological Health.

Viz.AI Contact is a computer-aided triage software solution that uses an artificial intelligence algorithm to analyse images for indicators associated with a stroke. AI algorithms are a type of clinical decision support software that can assist providers in identifying the most appropriate treatment plan for a patient’s disease or condition.

The FDA approval aligns with the agency’s longstanding comfort with image-based AI software, but it also signals a departure from 2012 guidance that categorises triage-based software as a higher risk functionality. In that regard, the approval goes farther than what the FDA has cleared in the past, which is a “big deal,” Bradley Merrill Thompson, an attorney with Epstein Becker & Green, said in an email to FierceHealthcare.

“[Triage] issues have been discussed for quite some time, so this is a big deal at least with regard to stroke,” he says. “But more generally, FDA seems to be warming to artificial intelligence used for triage which many companies will find is very good news.”

The app was cleared through the De Novo premarket review pathway, which oversees new devices that have been deemed a low to moderate risk. The approval also creates a new regulatory classification, allowing “subsequent computer-aided triage software devices with the same medical imaging intended use” to seek clearance through the premarket 510(k) processes.

The latest approval comes at a time when the FDA is establishing a long-awaited regulatory framework for CDS software. The agency’s guidance, released in December, has drawn criticism from

several health IT groups, including the CDS Coalition, led by Thompson, which said the guidance would lead to patient harm and force vendors to pull products off the market.

Source: FierceHealthcare
Image Credit: Pixabay

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