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ASIA EDITION

Third FDA Clearance for Zebra-Med's AI Solution for Brain Bleeds Alert

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Zebra Medical Vision, the deep learning medical imaging analytics company has announced that it has received its third FDA 510(k) clearance for the company's HealthICH product - an AI alert for intracranial hemorrhage (ICH), based on head CT scans.

The latest cleared product automatically identifies suspected internal brain bleeds based on non-contrast head CTs for triaging, significantly reduces turnaround time, and increases the radiologists' confidence in their diagnosis. The overall Multi-Modality AI Triage Solution by Zebra-med, is a first of its kind in the market that provide alerts for both CT scans and X-rays, and currently addresses two acute conditions: intracranial hemorrhages (head CTs), and pneumothorax (chest X-rays), which also received FDA clearance in the past month. Both Triage solutions and others, such as the FDA cleared calcium scoring product, are part of the AI1 "all-in-one" bundle that provides hospitals with a growing amount of AI tools at a fixed annual price and consistent service and support.

Intracranial hemorrhage accounts for about 10% to 20% of all strokes, and can occur as a result of traumatic injury (falls, crashes etc), ruptured arteries (aneurysms), stroke or cancer. It can result from injury within a vein or artery, or a combination of the two. Regardless of the cause, the timely and accurate diagnosis of active bleeding is essential for the successful care of these patients. Intracranial hemorrhage, or the common phrasing - brain bleed, is a devastating disease, with a high 30-day mortality rate that ranges from 35% to 52%. It is estimated that about 50% of this mortality occurs within the first 24 hours, emphasizing the importance of early detection and effective treatment in the Emergency Department.

The financial impact of early detection would be enormous given the fact that stroke cost the U.S. alone $34 billion annually, including the cost of healthcare services, medications, and lost productivity. The overall incidence of spontaneous ICH worldwide is 24.6 people in every 100,000 with approximately 40,000 to 67,000 cases per year in the United States.

Zebra-Med's intracranial hemorrhage triage solution can provide early detection of people who may have experienced a brain bleed. The algorithm is comprised of a unique, tailor-made neural network architecture designed to identify intracranial hemorrhage while tackling several challenges, such as relatively small bleed sizes and common artifacts (metal, motion artifacts) seen within the brain.

In busy Emergency Department environments, teleradiology services and other healthcare organizations that integrate Zebra-Med's 'All in one' (AI1) solution, radiologists can address these prioritized scans in a timely manner. Scans are forwarded automatically to the Zebra-Med server for analysis, the server then sends an alert of the positive cases directly to the worklist for prioritizing, thus saving physicians more than 80% of the time taken to reach the acute condition.

Eyal Gura, Zebra-med's CEO said, "We are thrilled to get a 3rd nod from the FDA in such a short time and to be able to add such an important new finding to our growing AI1 "all-in-one" package".

Dr. Keith White, Medical Director of Imaging Services at Intermountain Healthcare states, "We are working to improve our ability to quickly identify and respond to potentially dangerous clinical conditions through deployment of Zebra Medical Vision's intracranial hemorrhage solution"

Dr. Stanley Lu, MD, Radiologist and head of Neuroradiology at Monmouth Medical Center, part of RWJBarnabas Health states, "We have deployed Zebra Medical Vision's triage head CT solution that alerts our department of acute cases of intracranial hemorrhage. We have found the technology to be helpful as a second layer of analysis augmenting the clinical team's detection and response time for acute cases."

This is the second FDA clearance for Zebra's Multi-Modality AI Triage Solutions, which was received in May 2019 and focused on HealthPNX - an AI alert for pneumothorax (PNX), based on chest X-rays, enabling it to be the world's first AI chest x-ray triage product.

Zebra Medical's first FDA clearance, received in July of 2018, focuses on coronary calcium scoring, which can be an early sign for coronary artery disease (CAD). The growing number of FDA approvals within Zebra-Med's AI portfolio allows the company to expand its presence in the US market.