

NICO.LAB ready to revolutionise U.S. stroke care following FDA clearance

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The U.S. Food and Drug Administration (FDA) has cleared StrokeViewer LVO, NICO.LAB's artificial intelligence powered solution in stroke care, which was already TGA approved. StrokeViewer enables physicians to provide every stroke patient with the right treatment, as fast as possible. Two million brain cells die every minute until blood flow is restored (Saver, 2006), starting treatment earlier can make the difference between recovery or life-long disability.

The FDA approved the 510k application (FDA K200873) for StrokeViewer LVO, an artificial intelligence algorithm for fast triaging of stroke patients. StrokeViewer LVO is part of a complete set of tools to support physicians throughout the entire emergency stroke care workflow. It detects image characteristics associated with a Large Vessel Occlusion (LVO) and automatically alerts physicians.

StrokeViewer was developed by the Dutch medtech company NICO.LAB. The cloud-based solution uses artificial intelligence to support physicians in the emergency stroke setting. It analyses CT scans to detect haemorrhagic or ischemic stroke and sends a notification to the medical specialists involved just minutes after a patient arrives in the hospital. StrokeViewer provides physicians with a web-based diagnostic viewer to inspect the images and AI analysis and diagnose a stroke. This can be done on desktop, tablet or smartphone, in the hospital but also at home or any other place.

StrokeViewer has proven to reduce the time from hospital arrival to start treatment, leading to reduced patient disability in the short-term and more clot removal treatments performed.

"Medical specialists are under enormous pressure to make fast decisions day and night, which is not easy. Complicated assessment and interhospital communication sadly make life difficult for physicians motivated to treat stroke victims effectively" - said Merel Boers, CEO and co-founder of NICO.LAB.

Paul Lappin, chairman of NICO.LAB: *"We are convinced that AI will help save thousands of lives and billions of dollars in healthcare. We are already enabling hospitals in multiple countries in Europe, including the UK, and Australia. FDA approval is a great first step to achieving that in the United States as well."*

Stroke is a leading cause for serious long-term disability. In the UK, 100,000 people suffer a stroke each year, leaving them with physical and mental disabilities that create an enormous emotional, social, and financial burden on the community. The cost of stroke to society is around £26 billion a year (Stroke Association, 2018). In the U.S., the economic burden of stroke exceeds an astonishing \$100 billion per annum (Girotra, Lekoubou et al., 2020). Stroke incidence and associated costs are rising drastically due to an ageing population and increasing unhealthy lifestyle. NICO.LAB is dedicated to playing a crucial role in reducing these stroke related costs and improving quality of life of patients by combining human and artificial intelligence to revolutionise emergency stroke care.

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