



SENSOME RECEIVES FDA "BREAKTHROUGH DEVICE DESIGNATION" FOR ITS AI-POWERED STROKE GUIDEWIRE

PARIS, FRANCE - JUNE 21ST, 2021 – Sensome, the company pioneering the connected medical device revolution with the world's smallest biological tissue sensor, announced today that it has been granted a Breakthrough Device designation by the Center of Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) for its Clotild® Smart Guidewire System designed to improve the treatment of ischemic stroke patients.

Acute ischemic stroke, a leading cause of long-term disability, can be treated by removing the clot blocking the brain blood vessel using mechanical thrombectomy devices, which are guided from the groin over a wire to the blockage. To improve patient prognosis, the clot needs to be removed as fast as possible. Today, without knowledge of the clot's characteristics, the clot can only be removed on the first attempt in one out of three cases. Clotild® Smart Guidewire System integrating Sensome's AI-powered tissue sensor enables the guidewire to provide physicians with critical information on the clot.

The FDA Breakthrough Device Program is intended to help patients receive more timely access to breakthrough technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions. As part of this program, the FDA will provide Sensome with priority review and interactive communication on its path from device development to commercialization.

"This is a tremendous recognition by FDA that will boost our efforts to bringing Clotild® to patients in the US," indicates Franz Bozsak, CEO and co-founder of Sensome, "The first-in-human clinical trial of Clotild® is expected to start later this year outside the United States, which will take our device one step closer to improving care for ischemic stroke patients around the world."

ABOUT SENSOME

Sensome, a spin-off from CNRS and Ecole polytechnique (France), has developed a revolutionary sensor technology that turns invasive medical devices into connected healthcare devices. The company's sensing technology combines impedance-based micro-sensors with machine learning algorithms to instantly identify biological tissues with unequalled predictive reliability. Its first application is the Clotild® connected guidewire for the treatment of ischemic stroke. Sensome's sensor technology can be deployed in multiple other medical fields, such as interventional cardiology and oncology.

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