

MIVI Neuroscience Announces FDA IDE Clinical Study Approval For the MIVI Q Aspiration Catheter

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MIVI Neuroscience →
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EDEN PRAIRIE, Minn., June 9, 2020 /PRNewswire/ -- MIVI Neuroscience, a leading developer, and marketer of precision stroke therapy devices utilized by neurointerventionists around the world, announced today that the FDA has determined the company has provided sufficient data to support initiation of a human clinical study of the MIVI Q Aspiration Catheter in the United States. The EVaQ Study (A Prospective, Multi-Center, Single Arm Study to **E**valuate the **Q** Revascularization System for Neurointervention in Acute Ischemic Stroke) will assess the MIVI Q Catheter's ability to remove thrombus / blockages which cause large vessel occlusions (LVO) in the arteries of the brain.

The EvaQ Study is a single arm study with planned patient enrollment in up to 12 clinical centers located in the United States and additional sites in the European Union. The esteemed principal investigators for the EvaQ study are Dr. Lucas Eljovich of the Semmes Murphy Clinic in Memphis, Tennessee, Dr. Brian Jankowitz of Cooper University Health Care in Camden, NJ, and Professor Christophe Cognard of Purpan University Hospital in Toulouse, France.

"MIVI looks forward to working with FDA to incorporate the recommended protocol modifications in order to initiate and complete the EVaQ Study in the most rapid manner, and ultimately support a marketing clearance submission," said Bob Colloton, Chief Executive Officer of MIVI. "We are very excited about the future of the Q Catheter in the United States, building off the success of our devices in Europe."



About MIVI Neuroscience

MIVI Neuroscience, Inc. is focused on developing and commercializing superior clinical solutions for neurointerventional procedures. Adoption of endovascular stroke therapy procedures is growing significantly worldwide since compelling data from multiple large-scale randomized trials in 2015 and 2016 confirmed the value to rapidly clear occlusive clot from large cerebral vessels. MIVI's innovative product portfolio provides physicians with unique devices designed to improve patient outcomes in these procedures by reducing complications, shortening procedure times and expanding treatment to more patients. More information about MIVI can be found on the website, www.mivineuro.com.

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