

CoAxia Announces FDA Approval of Novel Treatment for Cerebral Vasospasm



NeuroFlo™ aortic catheter receives Humanitarian Device Exemption (HDE) for treatment of cerebral ischemia in acute cerebral vasospasm

Minneapolis, MN, April 13, 2005 – CoAxia, Inc. of Maple Grove, MN, announced the HDE approval of its new NeuroFlo™ dual balloon, aortic catheter for the treatment of cerebral ischemia in acute vasospasm. NeuroFlo represents the first interventional device approved for use as a treatment for patients with cerebral vasospasm following repair of an aneurysmal subarachnoid hemorrhage. The HDE approval by the FDA allows treatment of up to 4000 patients per year.

Cerebral vasospasm is a spasm or severe narrowing of blood vessels in the brain which may occur following repair of a brain aneurysm or cerebral hemorrhage. Vasospasm causes a reduction of cerebral blood flow, producing effects similar to those of strokes, and may cause permanent neurological disability or death. A significant fraction of the approximately 20,000 patients who undergo aneurysm repairs each year in the United States may develop vasospasm, and up to 10% of those with severe vasospasm will die. To date there are no approved treatments for this condition and existing therapies are associated with patient risks and inconsistent results.

The NeuroFlo catheter works by redirecting blood flow to the brain through restriction of blood flow in the descending aorta. The NeuroFlo catheter is inserted in the femoral artery and advanced to the aorta where its unique dual balloon design restricts a portion of the aortic flow. Clinical work to date has demonstrated that by partially occluding the descending aorta, the NeuroFlo catheter may increase perfusion in the cerebral vasculature by up to 30%, and thus potentially minimize or eliminate the severity of symptoms associated with the spasm.

Dr. Richard Atkinson, Director of the Sutter Institute for Medical Research at the Sutter Medical Center in Sacramento, CA, remarks, “Every doctor who takes care of patients with aneurysmal hemorrhage knows the frustration of the aneurysm being repaired but the patient then having a stroke or dying from delayed vasospasm. Our options have been difficult and often unsuccessful. The NeuroFlo catheter represents an entirely new approach which is easily done and gives us a new technique for helping patients with vasospasm.”

CoAxia is currently conducting a limited market release of the NeuroFlo system for vasospasm in the United States, Canada and Europe, where its initial user sites will participate in a clinical outcomes registry. Interested sites should contact CoAxia for further information.

“This HDE approval is a significant first step toward CoAxia’s goal of providing innovative cerebral perfusion augmentation therapies for both stroke and vasospasm patients”, says Rick Schallhorn, Vice-President of Marketing and Business Development for CoAxia.

CoAxia, Inc. is a privately held, development stage company focused on providing novel perfusion augmentation therapies which improve outcomes for patients with cerebral ischemia resulting from vasospasm, stroke and other conditions. In addition to the market release of NeuroFlo for vasospasm under HDE, CoAxia will initiate a multi-center, randomized, pivotal clinical trial of NeuroFlo as a treatment for stroke during the first half of 2005.

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