Monteris® Medical Press Release

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Monteris Medical's NeuroBlate System Receives 510(k) Clearance
MINNEAPOLIS

Monteris® Medical announced today that the US FDA has issued a second 510(k) clearance for their MRI-guided ablation device for brain tumors and other lesions. The NeuroBlate® System is a second generation device employing a surgical laser to ablate (lethally heat) diseased brain tissue with updated visualization provided by active MRI. A first generation system has been available in US hospitals since 2010.

Dr. Gene Barnett, MD, MBA, Burkhardt Chair in Neurosurgical Oncology, Cleveland Clinic Neurological and Cancer Institutes offered, "The NeuroBlate System will make laser ablation of brain lesions accessible to more neurosurgeons by virtue of its intuitive user interface and time-saving enhancements. Cleveland Clinic will soon be employing this tool to treat brain tumor patients who are seeking a minimally invasive option or are not candidates for traditional surgery."

"Monteris invested significant resources to provide customers with a laser ablation system that is faster and adapts to contemporary clinical workflow", said John Schellhorn, President and CEO. "The NeuroBlate System provides neurosurgeons controlled, 3-dimensional ablation via a powerful software platform. It supports surgical decision making during brain operations as well as providing post-procedure confirmation of the effects of the thermal therapy. We believe the NeuroBlate System will offer a new option for surgeons managing patients with brain tumors and other neurologic lesions".

About Monteris Medical

Monteris® Medical is a privately held medical device company dedicated to the development of innovative MRI-guided, laser-based brain lesion therapy. Monteris® Medical markets the NeuroBlate® System, a neurosurgical ablation device providing controlled therapy for difficult-to-treat brain tumors and epilepsy. Monteris also offers the AXiiiS® Stereotactic Miniframe; a single use platform for image-guided, stereotactic brain biopsy; and the AtamA™ Head Coil and Stabilization System for MRI-guided neurosurgical procedures requiring head fixation.
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