Intrinsic Imaging Core Lab Expertise Contributes to FDA Clearance of Medical Device

Neuroradiology interpretation and imaging core lab services contributed to FDA clearance of a neurointerventional medical device.

Bolton, MA / San Antonio, TX

Bolton, MA / San Antonio, TX — March 20, 2012 — Intrinsic Imaging, an ISO 9001:2008 certified and GAMP 5 compliant medical imaging core lab, announces today that its' expertise has contributed to the U.S. Food and Drug Administration's (FDA) clearance of a neurointerventional medical device.

During the clinical trial used as basis for FDA clearance of the device, Intrinsic Imaging provided imaging core lab services and its team of board certified neuroradiologists provided the complex interpretation and radiological assessment of the devices primary endpoints.

"Intrinsic Imaging is very proud to have acted as the medical imaging core lab on this clinical trial and that our therapeutic, operational and regulatory expertise has contributed to the FDA's clearance of this very important neurointerventional medical device." said Todd A. Joron, BSc., MBA, President and Chief Operating Officer, Intrinsic Imaging.

Neurointerventional medical devices are used for the prevention and treatment of various central nervous system (CNS) diseases and disorders including Alzheimer's disease, aneurysms, arteriovenous malformations, brain/CNS tumors, epilepsy, head trauma, hydrocephalus, Parkinson's disease, and stroke.

"Clinical trials involving disorders of the central nervous system often present a number of challenges due to the extensive knowledge base required and due to the complexity of image assessments and interpretations." said James Dix, MD., Medical Director, Neuroradiology at Intrinsic Imaging. "We are pleased our neuroradiology imaging core lab expertise was able to effectively contribute to the clearance of a very beneficial and effective new treatment for patients."

Intrinsic Imaging radiologists are deeply involved in the diagnosis and treatment of central nervous system disorders and perform hundreds of thousands of CNS related radiologic reviews annually. Their team of 10 full time board certified neuroradiologists specializes in all brain and spine pathology with broad experience and expertise in MRI, CT, diagnostic and interventional angiographic procedures, as well as PET imaging using novel CNS markers.

About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 650 board-certified and fellowship-trained physicians, Intrinsic Imaging's team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System,Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

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