Intrinsic Imaging Core Lab Expertise Contributes to Another FDA Approval

Core lab services and radiologic endpoint evaluation contributed to FDA premarket approval of a Class III breast cancer diagnostic device.

Bolton, MA / San Antonio, TX

Bolton, MA / San Antonio, TX — September 10, 2013 — Intrinsic Imaging, an FDA audited, ISO 9001 and ISO 13485 certified, and GAMP® 5 medical imaging core lab announces today that Intrinsic Imaging's core lab therapeutic, operational and regulatory expertise has contributed to another United States Food and Drug Administration (FDA) approval.

In this most recent approval, the FDA granted premarket approval (PMA) of a Class III medical device for the diagnosis of breast cancer. Premarket approval of Class III medical devices is the most stringent type of device marketing application required by the FDA.

During the Phase III clinical trial used as basis for this new FDA approval, Intrinsic Imaging provided its medical imaging core lab services, clinical trial expertise and 12 board-certified subspecialized radiologists to evaluate the trial's primary radiographic endpoints. In total, Intrinsic Imaging processed over 4,300 images, radiologic evaluations and associated case report forms.

At the conclusion of this trial, the FDA conducted an extensive routine five day audit of Intrinsic Imaging, and thoroughly inspected Intrinsic Imaging's entire quality management system (QMS) and all related clinical trial data to ensure compliance with all federal regulations. At the conclusion of the audit, Intrinsic Imaging was found to have conducted the clinical trial in complete compliance with all federal regulations and received zero 483 observations from the FDA.

"Class III medical devices include those that support or sustain human life and are of substantial importance in preventing impairment of human health," said Todd A. Joron, BSc., MBA, President and Chief Operating Officer, Intrinsic Imaging. "All of us at Intrinsic Imaging are very proud that our therapeutic, operational and regulatory expertise has contributed to the FDA's approval of this very important Class III medical device for breast cancer."

Intrinsic Imaging's medical device team is led by full time board-certified fellowship trained radiologists all of whom have experience with numerous medical devices in a variety of therapeutic areas, including but not limited to Cardiovascular, Central Nervous System, GI & Genitourinary, Musculoskeletal and Oncology. Further, in addition to its ISO 9001 certification, Intrinsic Imaging is also ISO 13485 certified specifically for providing medical imaging core labs services for clinical trials involving medical devices.

"Intrinsic Imaging's board-certified, breast imaging radiologists currently manage hundreds of thousands of breast related images annually and are responsible for the full complement of imaging and intervention as it relates to the evaluation, diagnosis, prognosis and progression of breast disease," said Dr. Richard Benedikt, Medical Director of Breast Imaging at Intrinsic Imaging. "Our team has extensive expertise in the field of breast cancer, and routinely performs all elements of breast cancer imaging including but not limited to full field digital mammography (FFDM) with Computer Assisted Detection (CAD), whole breast ultrasound, MRI, PET/CT, and nuclear medicine Imaging."

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 750 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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