



FOR IMMEDIATE RELEASE

FDA Grants Market Clearance for the LipiScan™ Coronary Imaging System Developed By InfraReDx, Inc. – *A novel spectroscopy system for the identification of lipid core containing plaques of interest in the coronary arteries*

BURLINGTON, Mass., April 29, 2008 - InfraReDx, Inc. announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its catheter-based *LipiScan™ Coronary Imaging System*. The LipiScan device uses near-infrared spectroscopy to identify lipid core containing plaques of interest in the coronary arteries in patients already undergoing cardiac catheterization. Such plaques, which cannot be detected by commonly-used tests such as a treadmill examination and even coronary angiography, are suspected to be the cause of most sudden cardiac deaths and non-fatal heart attacks.

The availability of this novel tool culminates a decade-long biomedical engineering effort to create an instrument that could perform spectroscopy in the arteries of patients with coronary artery disease. The identification of the chemical composition of coronary plaques is expected to be of value to cardiologists in the selection of medical, stenting or surgical therapy for coronary lesions. The device is also expected to be of value to the pharmaceutical industry as a means to assess the effect of novel anti-atherosclerotic agents on lipid core plaque burden.

"The InfraReDx team is pleased that the LipiScan System has been validated in tissue samples and a clinical study and has been cleared by the FDA for use in patients. We understand the great potential of interventional cardiology and anticipate that this novel tool will assist physicians with the complex decisions they face in the management of patients with coronary artery disease", says James E. Muller, M.D., cardiologist, co-founder, President and CEO of InfraReDx, Inc.

Dr. Muller noted that the creation of this novel device was greatly aided by the support and expertise of Sanderling Ventures of San Mateo, California. "Robert McNeil, Ph.D., Chairman of the Board of InfraReDx, and Timothy Mills, Ph.D., InfraReDx Board member are managing directors of Sanderling and both have extensive experience in medical device development," said Dr. Muller. "Sanderling was a seed investor in Advanced Cardiovascular Systems, a company that pioneered development of balloon angioplasty and was acquired by Guidant."

"While angioplasty and stenting were major advances, stenting has not been capable of preventing heart attacks due to the difficulty in identifying lesions likely to rupture and cause thrombosis. With the development of the LipiScan Coronary Imaging System,

Sanderling is again contributing to a major step forward in providing a useful tool with which interventional cardiologists may improve the care of cardiac patients.”

“There is a real unmet medical need to identify lipid core containing plaques of interest in the coronary arteries, which before now we could not do,” says James Goldstein, M.D., Director of Research and Education at William Beaumont Hospital in Royal Oak, Michigan, who is also an investigator in the SPECTACL clinical trial for the device and a consultant for InfraReDx. “The ability to detect lipid core containing plaques of interest may go a long way in providing information to help prevent heart attacks in the near future.”

How the LipiScan Coronary Imaging System Works

Near-infrared (NIR) spectroscopy is commonly used to measure the chemical composition of unknown substances. The LipiScan Coronary Imaging System utilizes advanced optical technology, much of it developed for telecom uses, to deliver and retrieve NIR light from coronary plaques. The light reflected back at different wavelengths is analyzed to detect the chemical composition of the coronary plaques. At the completion of the catheter pullback, the LipiScan console instantly displays the scan results on a “chemogram”, a digital color-coded map of the location and intensity of lipid core containing plaques of interest in the artery. A Lipid Core Burden Index is also reported, which is a measure of the total amount of lipid core containing plaques of interest in the coronary artery. The LipiScan catheter interrogates each artery in less than 2 minutes and does not require the interruption of the flow of blood.

Successful Clinical Trial Results

The SPECTACL clinical trial documented the similarity of near-infrared spectra obtained from 106 patients undergoing coronary angiography compared to spectra obtained in autopsy specimens in which the gold-standard of histology was available. For more information, visit the InfraReDx website at www.infraredx.com.

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About InfraReDx, Inc.

InfraReDx, Inc. is a privately-owned medical device company with expertise in near-infrared (NIR) spectroscopic technology and its application to coronary imaging. The company, located in Burlington, MA, was founded in 1998 to meet the unmet medical need for the detection and identification of lipid core containing plaques of interest in the coronary arteries. To meet this medical need, the Company developed The LipiScan Coronary Imaging System, an easy-to-use, catheter-based coronary imaging system that uses near-infrared spectroscopic technology to detect and characterize the composition of coronary artery plaques in patients undergoing catheterization. Funding for the development of the LipiScan System has been provided by a group of over 80 private investors and Sanderling Ventures. A Series C Funding round in 2007 raised \$17 million. For more information, visit the InfraReDx website at www.infraredx.com.

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