K072932
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510(K) SUMMARY
LipiScan Coronary Imaging System

Submitter Name: InfraReDx, Inc.

Submitter Address: 34 Third Avenue
Burlington, MA 01803

APR 25 2008

Contact Person: Steven J. Chartier, Director, Clinical and Regulatory Affairs

Phone Number: (781) 221-0053, ext. 349

Fax Number: (781) 272-5290

Date Prepared: April 21, 2008

Device Trade Name: LipiScan Coronary Imaging System

Device Common Name: Near Infrared Imaging System

Predicate Devices: InfraReDx NIR Imaging System (K052908)
Boston Scientific Galaxy IVUS System (K980851), Boston Scientific Atlantis SR Pro (K050577)
Volcano Eagle Eye Gold IVUS catheter (K051337), IVUS system (K042188)

Device Description: The LIpiScan Coronary Imaging System is comprised of the catheter, catheter accessories, pull-back and rotation device and laser console with accessories.

Intended Use: The LipiScan Coronary Imaging System is intended for the near-infrared examination of coronary arteries. The System is intended for the detection of lipid-core-containing plaques of interest. The System is intended for the assessment of coronary artery lipid core burden.

Device Technology Characteristics and Comparison to Predicate Device:
The LipiScan Coronary Imaging System utilizes the same basic catheter design as the predicate, the InfraReDx NIR Imaging System, cleared K052809. These devices have a similar intended use, use the same operating principal, incorporate the same basic catheter design, have the same shelf life, and are packaged using the same materials and processes. The modifications from the InfraReDx NIR Imaging System to the LipiScan Coronary Imaging System are the improved catheter design, improved user interface (including PBR and console), and the additional testing required to support an expanded indication for use.

Performance Data: The LipiScan Coronary Imaging System complies with applicable safety and performance standards, ISO 60601-1, ISO 60601-2-22, CSA22.2 No.601.1, CSA Z386-01, IEC 60825-1, ANSI Z136.1-2000 and ISO 10993 (for transient blood contacting devices). Further preclinical testing has shown that the product can function as intended and meets all internal design specifications.

Conclusion: The LipiScan Coronary Imaging System has similar indications statements as the predicate devices. All are used for imaging of the coronary vasculature. The functionality of the LipiScan Coronary Imaging System and predicate devices is identical. The catheter accesses the coronary vasculature via the femoral or radial access site and tracks on the existing guidewire as used during routine PCI. The device output is an image of the artery wall, as an adjunct to coronary angiography, and is similar to the predicate devices. *Ex vivo* and *in vivo* data is presented to support expanded indications for use. Therefore the LipiScan Coronary Imaging System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 2008

InfraReDx, Inc.
c/o Mr. Steven J. Chartier
Director, Clinical and Regulatory Affairs
34 Third Ave.
Burlington, MA 01803

Re: K072932
Trade/Device Name: LipiScan Coronary Imaging System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: OGZ
Dated: March 5, 2008
Received: March 6, 2008

Dear Mr. Chartier:

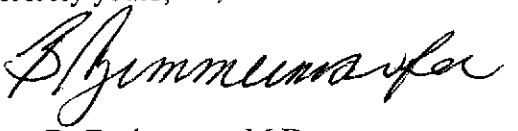
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K072932

Device Name: **LipiScan Coronary Imaging System**

Indications for Use:

The LipiScan Coronary Imaging System is intended for the near-infrared examination of coronary arteries in patients undergoing invasive coronary angiography. The System is intended for the detection of lipid-core-containing plaques of interest. The System is intended for the assessment of coronary artery lipid core burden.

Perscription Use __X__ (21 CFR 801 Subpart D) AND/OR Over the Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evalution (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072932