510(K) SUMMARY K052908
InfraReDx Near Infrared (NIR) Imaging System

JUN 2 3 2006

Submitter Name:	InfraReDx
Submitter Address:	34 Third Avenue Burlington, MA 01803
Contact Person:	Nandini Murthy, V.P. Clinical and Regulatory Affairs
Phone Number:	(781) 221-0053, Extn 221
Fax Number:	(781) 272-5290
Date Prepared:	October 13, 2005 (Amended: June 8, 2006)
Device Trade Name:	InfraReDx Near Infrared (NIR) Imaging System, Model MC-5
Device Common Name:	Near Infrared (NIR) Imaging System
Predicate Devices:	Boston Scientific Galaxy IVUS System, Boston Scientific Atlantis SR, SR Pro and SR Plus IVUS catheter Volcano Revolution and Eagle Eye Gold IVUS catheter, IVUS system Baxter Imagecath Coronary Angioscope American Edwards Angioscopy catheter/system Cardio-Optics CSA System
Device Description:	The InfraReDx Near Infrared (NIR) Imaging system is comprised of the catheter, catheter accessories, pull-back and rotation device and laser console with accessories.
Intended Use:	The InfraReDx Near Infrared (NIR) Imaging System is intended for the near infrared imaging of the coronary arteries.
Performance Data:	The InfraReDx Near Infrared (NIR) 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 InfraReDx Near Infrared (NIR) Imaging System has similar indications statements as the predicate devices. All are used for imaging of the coronary vasculature. The functionality of the InfraReDx 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, as an adjunct to coronary angiography, and is similar to the predicate devices. Therefore the InfraReDx NIR 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

JUN 23 2006

InfraReDx, Inc.
Ms. Nandini Murthy
Vice President, Clinical and Regulatory Affairs
34 Third Avenue
Burlington MA 01803

Re: K052908
Trade/Device Name: InfraReDx NIR Imaging System, Model MC-5
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II (performance standards)
Product Code: DQO
Dated: April 24, 2006
Received: April 25, 2006

Dear Ms. Murthy:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (if known): K052908

Device Name: InfraReDx Near Infrared (NIR) Imaging System

Indications For Use:

The InfraReDx NIR System is intended for the near infrared imaging of the coronary arteries.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052908