



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 23, 2014

Infraredx, Inc.
Steven Chartier
Vice President Operations, Quality and Regulatory
34 Third Ave.
Burlington, MA 01803

Re: K133897
Trade/Device Name: TVC Imaging System, TVC Insight Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OGZ, OBJ
Dated: March 28, 2014
Received: March 31, 2014

Dear Steven 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

The logo of the U.S. Food and Drug Administration (FDA), featuring the letters 'FDA' in a stylized, bold font with a diagonal line through the 'A'.

for Bram D. Zuckerman, M.D.

Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use

510(k) Number (if known): K133897

Device Name: TVC Imaging System™

Indications for Use:

1. The TVC Imaging System™ is intended for the near-infrared examination of coronary arteries in patients undergoing invasive coronary angiography.
 - a. The System is intended for the detection of lipid-core-containing plaques of interest.
 - b. The System is intended for the assessment of coronary artery lipid core burden.
2. The System is intended for ultrasound examination of coronary intravascular pathology.
 - a. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Prescription 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 Evaluation (ODE)

Date:
2014-04-23
10:37:54
-04'00'