DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 21, 2017

Infraredx, Inc.
Stephen Sum
Sr. VP of Technology Innovation and Regulatory Affairs
34 Third Avenue
Burlington, Massachusetts 01803

Re: K163345
Trade/Device Name: TVC Imaging System, TVC-MC10/TVC-MC10i
TVC Catheter, TVC-C195-42
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OGZ, IYO
Dated: May 16, 2017
Received: May 19, 2017

Dear Stephen Sum:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163345

Device Name
TVC Imaging System™, TVC-MC-10/TVC-MC-10i
TVC Catheter, TVC-C195-42

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5: Traditional 510(k) Summary

K163345

Submitted by: Infraredx, Inc.

Contact Person:
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Date of Summary: November 28, 2016

Device Trade Name: TVC Imaging System™, TVC-MC-10 / TVC-MC-10i
TVC Catheter, TVC-C195-42

Common or Usual Name: Ultrasonic Pulsed Echo Imaging System
Diagnostic Intravascular Catheter

Classification: 21 CFR 892.1560
21 CFR 870.1200

Class: II

Product Code: IYO, OGZ

Predicate Device(s): TVC Imaging System (K141682)

Device Description: The TVC Imaging System™ is an intravascular imaging device with the ability to simultaneously assess vessel composition and structure using near-infrared spectroscopy (NIRS) and intravascular ultrasound (IVUS). This dual-modality instrument performs near-infrared spectroscopic analysis of the vessel to detect lipid core-containing plaques of interest (LCP) displayed in a map called a Chemogram, and simultaneously generates high resolution IVUS images that display structural details of the vessel and plaque in transverse and longitudinal views.

Indication 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.

Technological Characteristics: The TVC Imaging System™ is composed of three main components: the TVC Catheter, the TVC Controller (Pullback and Rotation Device (PBR)), and the TVC Console. These three interconnected components work together to produce dual images of NIRS and IVUS in a single scan of the vessel.

The proposed device has the same technological characteristics and is similar in design and configuration as compared to the currently marketed predicate device.

General Characteristics:			
Characteristic	**Predicate TVC-C195-32 and TVC-MC9, MC9i (K141682)**	**New Device TVC-C195-42 and TVC-MC10, MC10i**	**Comparison with Predicate Device**
Product Function	Near Infrared and Ultrasound Imaging System	Near Infrared and Ultrasound Imaging System	Same
Intended Use	The TVC 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. The System is intended for ultrasound examination of coronary intravascular pathology. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.	The TVC 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. The System is intended for ultrasound examination of coronary intravascular pathology. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.	Same
Where Used	Coronary	Coronary	Same
System Components	NIR/IVUS Catheter Portable or Fixed Console (Laser, SBC, power supply) and Controller	NIR/IVUS Catheter Portable or Fixed Console (Laser, SBC, power supply) and Controller	Same
Classification	Catheter – Product Code OGZ 21 CFR 870.1200 System Product Code IYO 21 CFR 892.1560	Catheter – Product Code OGZ 21 CFR 870.1200 System Product Code IYO 21 CFR 892.1560	Same
Clinical data in 510(k)	No	No	Same

Catheter Characteristics:			
Characteristic	**Predicate** **TVC-C195-32 and TVC-MC9, MC9i (K141682)**	**New Device** **TVC-C195-42 and TVC-MC10, MC10i**	**Comparison with Predicate Device**
Usable Length	160 cm	160 cm	Same
Sheath Distal Tip Profile	2.4 F	2.4 F	Same
Guidewire rail length	2.5 cm	1.2 cm	Substantially equivalent
Imaging window profile	3.2 F	3.2 F	Same
Imaging core pullback	12 cm	15 cm	Substantially equivalent
Number of RO Marker Bands	1 RO marker (0.5cm from distal tip)	1 RO marker (0.5cm from distal tip)	Same
Maximum guidewire OD	0.014 in.	0.014 in.	Same
Minimum guide catheter I.D.	6 F	6 F	Same
Method of Sterilization	EtO	EtO	Same
Packaging	Sealed tray/pouch	Card/pouch	Substantially equivalent
Materials supplied in sterile packaging	Intravascular NIR/IVUS catheter Priming accessory Controller sterile barrier	Intravascular NIR/IVUS catheter Priming accessory Controller sterile barrier	Same
Transducer Center Frequency	50MHz	50MHz	Same

Controller and Console Characteristics:			
Characteristic	**Predicate** **TVC-C195-32 and TVC-MC9, MC9i (K141682)**	**New Device** **TVC-C195-42 and TVC-MC10, MC10i**	**Comparison with Predicate Device**
Imaging Mode	Near Infrared light Ultrasound	Near Infrared light Ultrasound	Same
Output	NIR light RF Ultrasound	NIR light RF Ultrasound	Same
Hardware Components	CPU with 4GB RAM 1 Monitor and 1 Touchscreen Monitor Swept Source Laser	CPU with 16GB RAM 1 Monitor and 1 Touchscreen Monitor Swept Source Laser	Substantially equivalent
Laser Type	Swept Source Semiconductor Laser	Swept Source Semiconductor Laser	Same
Imaging element pullback speed	0.5 mm/s	0.5, 1.0, and 2.0 mm/s	Substantially equivalent
Pullback Distance	120mm	150mm	Substantially equivalent
Controller Housing	No handle	Handle	Substantially equivalent
Controller User Interface	LED lights	LCD screen	Substantially equivalent

Performance Testing (Bench):

Biocompatibility

The biocompatibility evaluation was conducted for an external communicating device in circulating blood, with a limited contact duration of $\leq$ 24 hrs. The series of testing was conducted using the TVC Catheter and utilizing Good Laboratory Practice (GLP). The testing procedures are based on the requirements of:

- ASTM F756-13 Standard Practices for Assessment of Hemolytic Properties of Materials
- ISO 10993-4: 2002: Biological evaluation of medical devices - Part 4: Selection of tests for interaction with blood, as amended 2006
- ISO 10993-5: 2009: Biological Evaluation of Medical Devices - Part 5: Tests for Cytotoxicity, in vitro methods
- ISO 10993-10: 2010: Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and skin sensitization
- ISO 10993-11: 2006: Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Sterilization and Shelf Life

This sterilization re-qualification was conducted using the TVC Catheter and packaging. Results reported meet the criteria defined in ISO 11135: 2014.

The shelf life evaluation conducted on the TVC Catheter passed all catheter and accessory specifications. The data obtained support a 6 month shelf life for the TVC Catheter.

Performance Testing

Verification and validation testing was performed on the TVC Imaging System™ with the TVC Catheter and Controller to demonstrate that the new catheter and modified controller met all design specifications. The results of the tests showed the TVC Catheter (TVC-C195-42) and Controller passed all tests conducted and met specification.

Validation testing of the Commercial UI Software and Controller Software with the modifications listed above showed passing results for all specifications.

Performance Testing (Animal):

An in vivo assessment was conducted where swine underwent a single surgical procedure on Day 0 in which the Infraredx TVC Catheter was placed and a pullback was performed in each of 3 coronary arteries per animal. There were no safety concerns in the swine coronary artery model 6 days after imaging with the Infraredx TVC Catheter.

An additional in vivo assessment was conducted where swine underwent a single interventional procedure in which stents were implanted in the coronary arteries in such a manner as to appose a portion of the stent to the vessel wall and malappose another portion of the stent. Infraredx TVC Catheter imaging was performed through the implanted stent to determine apposition and malapposition of the stent with each of the test and predicate catheters. The Infraredx TVC Catheter and MC10 Console and Controller (PBR) were determined to meet the objectives of this study and found to be

	equivalent to the predicate product.
Performance Testing (Clinical):	None Provided
Substantial Equivalence Rationale:	There are no proposed changes to the intended use of this product, nor any changes to the scientific principles of operation, principal technological characteristics, or safety. The non-clinical and pre-clinical testing performed on the proposed device indicates that it is safe and effective, and is substantially equivalent to the predicate device.