December 7, 2021

Infraredx, Inc.
Stephen Sum
Sr. VP of Clinical, Regulatory & Research
28 Crosby Drive, Suite 100
Bedford, Massachusetts 01730

Re: K213303
Trade/Device Name: Makoto Intravascular Imaging System™, TVC-MC10/TVC-MC10i
Dualpro IVUS + NIRS Imaging Catheter™, TVC-C195-42
Peripheral 014 Imaging Catheter, TVC-E195-42
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, OGZ, OBJ
Dated: September 30, 2021
Received: October 4, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213303

Device Name
Makoto Intravascular Imaging System™, TVC-MC10/TVC-MC10i
Dualpro IVUS + NIRS Imaging Catheter™, TVC-C195-42
Peripheral 014 Imaging Catheter, TVC-E195-42

Indications for Use *(Describe)*

Indications for Use:

1. The Makoto Intravascular 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.
c. The System is intended for the identification of patients and plaques at increased risk of major adverse cardiac events.

2. The System is intended for ultrasound examination of coronary and peripheral intravascular pathology.
a. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary and peripheral interventional procedures. The System is not indicated for use in the cerebral vessels.

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)

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Contents

Traditional 510(k) Summary

Submitted by:	Infraredx, Inc.
Contact Person:	Stephen Sum Sr. VP of Clinical, Regulatory & Research Infraredx, Inc. 28 Crosby Drive, Suite 100 Bedford, MA 01730 Tel: 781.345.9651 Fax: 781.345.9551 Email: ssum@infraredx.com
Date of Summary:	December 7, 2021
510(k) Number:	K213303
Device Trade Name:	Makoto Intravascular Imaging System™, TVC-MC10/TVC-MC10i Dualpro IVUS + NIRS Imaging Catheter™, TVC-C195-42 Peripheral 014 Imaging Catheter, TVC-E195-42
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, OBJ
Predicate Device(s):	Makoto Intravascular Imaging System™, TVC-MC10/TVC-MC10i Dualpro IVUS + NIRS Imaging Catheter™, TVC-C195-42 (K183599)
Device Description:	The Makoto Intravascular 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 Makoto Intravascular 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. c. The System is intended for the identification of patients and plaques at increased risk of major adverse cardiac events.

2. The System is intended for ultrasound examination of coronary and peripheral intravascular pathology.
   a. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary and peripheral interventional procedures. The system is not indicated for use in the cerebral vessels.

Technological Characteristics:

The Makoto Intravascular Imaging System™ is composed of three main components: the Catheter, the Controller (Pullback and Rotation Device (PBR)), and the 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 scientific principles of operation, principal technological characteristics, and safety profile as the currently marketed predicate device (K183599). Only minor design changes to the predicate device have been implemented. The tables below compare the general, catheter, controller, and console characteristics of the proposed and predicate devices.

General Characteristics:				
Characteristic	**PROPOSED DEVICE** **Infraredx** **TVC-E195-42, TVC-C195-42 & TVC-MC10/ MC10i**	**PREDICATE DEVICE** **Infraredx** **TVC-C195-42 & TVC-MC10/ MC10i** **(K183599)**	**REFERENCE** **Philips Volcano** **Visions PV .014P RX Digital IVUS Catheter** **(K152829)**	**Comparison with Predicate Device**
Product Function	Near Infrared and Ultrasound Imaging System	Near Infrared and Ultrasound Imaging System	Digital Intravascular Ultrasound Catheter	Same
Intended Use	The Makoto Intravascular 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 the identification of patients and plaques at increased risk of major adverse cardiac events. The System is intended for ultrasound examination of coronary and peripheral intravascular pathology. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary and peripheral interventional procedures. It is not intended for use in cerebral vessels.	The Makoto Intravascular 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 the identification of patients and plaques at increased risk of major adverse cardiac events. 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 Visions® PV.014P RX Digital IVUS Catheter is designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in the cerebral vessels. The Visions® PV.014P RX Digital IVUS Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.	Substantially Equivalent
Where Used	Coronary and Peripheral	Coronary	Peripheral	Substantially Equivalent

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	Diagnostic Intravascular Catheter Diagnostic Ultrasound Transducer	Same
Classification	Catheter – Product Code OGZ, OBJ 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	Catheter – Product Code OBJ 21 CFR 870.1200 Transducer Product Code ITX 21 CFR 892.1570	Substantially Equivalent

Catheter Characteristics:				
Characteristic	**PROPOSED DEVICE** **Infraredx** **TVC-E195-42, TVC-C195-42 & TVC-MC10/ MC10i**	**PREDICATE DEVICE** **Infraredx** **TVC-C195-42 & TVC-MC10/ MC10i** **(K183599)**	**REFERENCE** **Philips Volcano Visions PV .014P RX Digital IVUS Catheter** **(K152829)**	**Comparison with Predicate Device**
Usable Length	160 cm	160 cm	150 cm	Same
Sheath Distal Tip Profile	2.4 F	2.4 F	1.5 F (0.019”)	Same
Guidewire rail length	1.2 cm	1.2 cm	24 cm	Same
Imaging window profile	3.2 F	3.2 F	3.5 F	Same
Imaging core pullback	15 cm	15 cm	N/A	Same
Number of RO Marker Bands	1 RO marker (0.5cm from distal tip)	1 RO marker (0.5cm from distal tip)	3 RO markers	Same
Max. guidewire OD	0.014 in.	0.014 in.	0.014 in.	Same
Min. guide catheter ID	6 F	6 F	5F	Same
Method of Sterilization	EtO	EtO	EtO	Same
Materials supplied in sterile packaging	Intravascular NIR/IVUS catheter Priming accessory Controller sterile barrier	Intravascular NIR/IVUS catheter Priming accessory Controller sterile barrier	Intravascular IVUS catheter Priming accessory	Same

Shelf Life	36 months	18 months	[Unknown]	Substantially Equivalent
Transducer Center Frequency	50MHz	50MHz	20 MHz	Same
Catheter rotating hub color	TVC-E195-42: Blue TVC-C195-42: Green	Green	N/A	Substantially Equivalent

Console & Controller Characteristics:			
Characteristic	**PROPOSED DEVICE** **Infraredx** **TVC-E195-42, TVC-C195-42 and TVC-MC10/ MC10i**	**PREDICATE DEVICE** **Infraredx** **TVC-C195-42 and TVC-MC10/ MC10i** **(K183599)**	**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 16GB RAM 1 Monitor and 1 Touchscreen Monitor Swept Source Laser	CPU with 16GB RAM 1 Monitor and 1 Touchscreen Monitor Swept Source Laser	Same
Laser Type	Swept Source Semiconductor Laser	Swept Source Semiconductor Laser	Same
Imaging pullback speed	0.5, 1.0, and 2.0 mm/s	0.5, 1.0, and 2.0 mm/s	Same
Pullback Distance	150mm	150mm	Same
Controller Housing	Handle	Handle	Same
Controller RFID	Enabled for catheter type identification	Disabled	Substantially Equivalent
Controller User Interface	LCD screen	LCD screen	Same
Graphical User Interface	NIRS-IVUS image for coronary scanning (TVC-C195-42) IVUS image only for peripheral scanning (TVC-E195-42)	NIRS-IVUS image for coronary scanning	Substantially Equivalent

Performance Testing (Bench):

Biocompatibility

There are no changes to the patient contact materials of the device compared to the predicate (K183599), and therefore no changes to its biocompatibility. The biocompatibility testing reported for the predicate device still applies.

The biocompatibility evaluation of the predicate TVC-C195-42 catheter was conducted for an external communicating device in circulating blood, with a limited contact duration of ≤ 24 hrs. The series of testing was conducted utilizing Good Laboratory Practice (GLP) following ISO 10993 and ASTM standards.

The proposed catheter (TVC-E195-42) is identical in design and materials to the predicate catheter (TVC-C195-42) with the exception of the color of the rotating hub (non-patient contact). Thus, the biocompatibility testing performed for the predicate device also applies to the proposed device.

Sterilization and Shelf Life

The predicate catheter (TVC-C195-42) is sterilized using ethylene oxide gas (EtO). The proposed catheter (TVC-E195-42) will be sterilized in the same manner.

The sterilization qualification for the predicate was last conducted in 2020 using the TVC-C195-42 catheter and packaging. Results reported met the criteria defined in ISO 11135: 2014. A successful requalification via document review was more recently performed in 2021.

The shelf life of the TVC-C195-42 catheter was re-evaluated to augment the shelf life from 18 to 36 months compared to the predicate (K183599) by accelerated aging per ASTM F1980. The TVC-C195-42 passed all catheter and accessory specifications to support a 36-month shelf life.

The proposed catheter (TVC-E195-42) is identical in design and materials to the predicate catheter (TVC-C195-42) with the exception of the color of the rotating hub. The packaging of the proposed catheter is also the same as that of the predicate except for the label content. Thus, the sterilization qualification and the shelf life validation performed for the predicate device also apply to the proposed device.

Performance Testing

There are no changes or modifications that significantly affect the safety or effectiveness of the system compared to the predicate (K183599). The proposed device has the same technological, engineering, and performance specifications. Only minor modifications have been made to the device since the market clearance of the predicate.

Minimal design changes are proposed to support the additional indication for IVUS imaging of the peripheral vasculature, namely:

1. Distinguish coronary and peripheral catheters by hub color for easy visual identification.
2. Program radio-frequency identification (RFID) chip in catheter hub to identify catheter as either coronary or peripheral.
3. Activate RFID in controller to identify connected catheter as either coronary or peripheral.
4. Modify graphical user interface (GUI) so that only IVUS image is displayed when peripheral catheter is connected.

All modifications were documented, reviewed, and approved per the Quality System Regulation. Where appropriate, modifications were tested according to verification and validation protocols and results recorded and documented per the Quality Management System.

EMC and Electrical Safety Testing

The proposed device differs from the predicate device electrically in the implementation of radio-frequency identification (RFID) of the catheter connected to the system.

Electromagnetic compatibility (EMC) testing was conducted on the proposed device (TVC-MC10 System and TVC-E195-42 Catheter). Electrical Safety was not repeated on the proposed device as the changes (i.e., implementation of RFID) to the predicate had no impact on Electrical Safety.

The proposed device met all EMC requirements per IEC 60601-1-2:2014 (4th Ed).

Performance Testing (Animal):

There are no changes to the device requiring *in vivo* animal testing. The animal testing reported for the predicate device (K163345) still applies.

The *in vivo* animal assessment of the predicate device was conducted on swine. There were no safety concerns in the swine coronary artery model after imaging with the TVC-C195-42 catheter, which is identical in design (except for hub color) to the proposed TVC-E195-42 catheter. Additionally, an assessment of image quality and stent apposition were successfully performed.

The proposed TVC-E195-42 catheter is identical in form, fit, and function to that of the predicate catheter TVC-C195-42 catheter. The above animal studies present a worst-case (coronary) model for the proposed TVC-E195-42 peripheral catheter in terms of safety and performance. Therefore, additional animal testing for the TVC-E195-42 catheter was not performed.

Performance Testing (Clinical):

No prospective clinical trials were conducted in support of this Traditional 510(k).

Substantial Equivalence Rationale:

The proposal is to expand the indications for use of the device as indicated by the underscoring below:

The Makoto Intravascular 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.
c. The System is intended for the identification of patients and plaques at increased risk of major adverse cardiac events.

The System is intended for ultrasound examination of coronary and peripheral intravascular pathology.

a. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary and peripheral interventional procedures. The System is not intended for cerebral vessels.

There are no proposed changes that significantly affect the safety or effectiveness of the system compared to the predicate (K183599). The proposed device has the same technological, engineering, and performance specifications. The testing performed on the proposed and predicate devices indicates that the proposed device is safe and effective, and is substantially equivalent to the predicate device.