May 22, 2020

Philips Image Guided Therapy Corporation
Mary Stanners
Regulatory Affairs Specialist
3721 Valley Centre Drive Ste 500
San Diego, California 92130

Re: K200410
Trade/Device Name: Reconnaissance PV .018 OTW Digital IVUS Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, ITX
Dated: February 18, 2020
Received: February 19, 2020

Dear Mary Stanners:

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,

Mark Fellman
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200410

Device Name
Reconnaissance PV .018 OTW Digital IVUS Catheter

Indications for Use *(Describe)*

The Reconnaissance PV .018 Digital IVUS catheter is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicted for use in cerebral vessels.

The Reconnaissance PV .018 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

SPONSOR:	Philips Image Guided Therapy Corporation 3721 Valley Centre Drive, Suite 500 San Diego, CA 92130
CONTACT/SUBMITTER:	Mary Stanners, RAC Regulatory Affairs Specialist Philips Image Guided Therapy Corporation 3721 Valley Centre Drive, Suite 500 San Diego, CA 92130 Tel: (858) 764-1296
DATE PREPARED:	May 13 , 2020
DEVICE:	Intravascular Ultrasound Catheter
TRADE NAME:	Reconnaissance PV .018 OTW Digital IVUS Catheter
COMMON NAME:	Intravascular Ultrasound Catheter
CLASSIFICATION:	21 CFR 870.1200 OBJ: Diagnostic Intravascular Catheter 21 CFR 892.1570 ITX: Diagnostic Ultrasound Transducer
PREDICATE DEVICES:	Visions PV .018 Digital IVUS Catheter (K150442) Visions EEP/EEP-ST/Visions PV .014P RX Digital IVUS Catheter (K143701)
REFERENCE DEVICE:	Visions PV .035 Digital IVUS Catheter (K153094)
DEVICE DESCRIPTION:	The Reconnaissance PV .018 OTW IVUS Catheter is an over-the-wire intravascular imaging catheter with a digital ultrasound transducer at the distal end and has a transducer that utilizes a 64-element cylindrical array that radiates acoustic energy into the surrounding tissue and detects the subsequent echoes. The information from the echoes is used to generate real-time images of the peripheral vessels. The Reconnaissance PV .018 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.

	The catheter has 150cm working length and a hydrophilic coating at the distal 40 cm to assist the clinician in advancing the catheter to the desired location. The minimum guide sheath is 5F (0.074") and the maximum guide wire Outer Diameter (OD) is 0.018" (0.46 mm). At the proximal end, there is a PIM Connector and Y Connector (aka Y-Arm). The Y-Arm allows the catheter to incorporate the PIM Connector while still serving as an over-the-wire design. A Luer/hub fitting (aka the Y-Arm) is attached to the proximal end of the catheter via an integrated strain relief and provides a channel for the scanner lead wires, routed from the cylindrical ultrasound transducer array, to interface electrically with the patient interface module (PIM) connector. The Visions® PV 0.018 Catheter may only be used with Philips Imaging Systems, such as the CORE Series Precision Guided Therapy Systems such as the IntraSight System.
INDICATIONS FOR USE:	The Reconnaissance PV .018 Digital IVUS catheter is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicted for use in cerebral vessels. The Reconnaissance PV .018 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.
COMPARISON OF CHARACTERISTICS	The Reconnaissance PV .018 OTW catheter is a modification to the currently marketed PV .018 Digital IVUS Catheter cleared under K150442 to an over the wire design. Philips has prior experience with an over the wire digital IVUS catheter having obtained clearance and marketed the PV .035 Digital IVUS catheter (K153094). The subject device and predicates are all phased array catheters using synthetic Aperture Intravascular technology. The subject and predicates devices have the same principle of operation. The devices incorporate an ultrasound transducer array located near the distal tip of the catheter. The array radiates acoustic energy into the surrounding tissue and detects the subsequent ultrasonic echoes. The information from the echoes is transmitted to compatible imaging systems and is used to generate real-time images of peripheral vessel lumens and wall structures. The subject device scanner and electrical components are the same as those used in the predicate device Visions EEP/EEP-ST/Visions PV .014P RX Digital IVUS Catheter (K143701). There are differences in the catheter materials and coating of the Reconnaissance catheter as compared to the predicates. The

	materials and coating were tested and design verification, shelf life, GLP design validation results demonstrate performance and safety.

PERFORMANCE DATA:	Performance testing completed for a determination of substantial equivalence include the following:
	• Design Verification-The Reconnaissance catheter was verified to pre-determined acceptance criteria using appropriate sample sizes.
	• Biocompatibility- Cytotoxicity, Sensitization, Irritation, Pyrogenicity, Acute Systemic Toxicity, and Hemocompatibility tests were performed. Based on the biocompatibility results, the intended use, risk, materials and interactions, demonstrated that the Reconnaissance catheter is biocompatible and acceptable for use.
	• Sterilization- The Reconnaissance catheter met the pre-determined specifications for effectively achieving a SAL of 10^{-6}.
	• Shelf Life- The shelf life testing results demonstrated that the Reconnaissance device meets the specific requirements. The design is acceptable for its intended use during the prescribed shelf life of the device.
	• Packaging Validation- The sterility and performance of the devices were maintained with the packaging system design and this design is deemed acceptable for packaging and shipping of the Reconnaissance catheter.
	• Design Validation (GLP Animal) - The Reconnaissance catheter met and passed all user requirements for each individual test case. Vascular injury was not observed in any treated vessel, nor were there abnormalities of any grossly examined tissues. Based on the analysis of the study results, it is concluded that the Reconnaissance catheter was safe and performed as intended.
	• Design Validation (Usability)-All knowledge-based questions were answered with a success rating higher than the predetermined specifications. The Human Factors Usability Testing, Product Validation Testing, and Labeling Validation Testing has met the acceptance criteria demonstrating that the Reconnaissance catheter conforms to its
	  • Intended Use
	  • Usability Requirements
	  • Defined User Requirements

CONCLUSIONS	Based on the testing results, the Reconnaissance Digital IVUS Catheter is substantially equivalent to the predicates. The data support the performance and safety of the device. Verification/validation demonstrate that the Reconnaissance catheter will perform as intended in the defined conditions.