September 2, 2020

Philips Image Guided Therapy Corporation
% Rand Daoud
Regulatory Affairs Specialist, 4
Philips Ultrasound, Inc.
22100 Bothell Everett Hwy
Bothell, Washington 98021

Re: K200812
Trade/Device Name: VeriSight Intracardiac Echocardiography (ICE) Catheter, and VeriSight Pro ICE Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: August 13, 2020
Received: August 17, 2020

Dear Rand Daoud:

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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200812

Device Name
VeriSight/VeriSight Pro Intracardiac Echocardiography (ICE) Catheter

Indications for Use *(Describe)*

The VeriSight/VeriSight Pro ICE Catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous 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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Philips Image Guided Therapy Corporation

K200812 - 510(k) Summary

Submitter Information:

Date Prepared	August 13, 2020
Manufacturer Name and Address	Philips Image Guided Therapy Corporation 2870 Kilgore Road Rancho Cordova, CA 95670
Establishment Registration Number	2939520
Primary Contact/Submitter Information	Rand Daoud Regulatory Affairs Specialist, 4 TEL: 1-858-720-4049 EMAIL: rand.daoud@philips.com Philips Image Guided Therapy Corporation 3721 Valley Center Dr. Suite 500 San Diego, CA 92130

Subject Device Information:

Trade Name	VeriSight Intracardiac Echocardiography Catheter, VeriSight Pro Intracardiac Echocardiography Catheter
Common Name	Intravascular Ultrasound Catheter
Regulation Description	Diagnostic intravascular catheter
Regulation Number	870.1200
Product Code	OBJ
Device Class	Class II
Classification Panel	Cardiovascular

Predicate Device: K170263 - Siemens AcuNav Diagnostic Ultrasound Catheter 8F, 10F

Reference Devices: K173618 - ACUSON AcuNav Volume ICE Catheter

Subject Device Description:

The Intracardiac Echocardiography (ICE) System comprises of the VeriSight/VeriSight Pro ICE Catheters, the ICE PIM, and the EPIQ Diagnostic Ultrasound System (cleared under K202216).

The VeriSight/VeriSight Pro Intracardiac Echocardiography (ICE) catheters are sterile, disposable, and for single use only. The catheter's distal end has an ultrasound transducer providing 2D and/or 3D imaging capabilities. A handle, located at the proximal end of the catheter, has two steering wheels that can be manually operated to control four-way articulation of the distal segment in anterior, posterior, left and right directions. The catheter has a 9 French (F) shaft and a usable length of 90 cm.

The VeriSight and VeriSight Pro ICE Catheters are identical in all regards (material, processing, assembly and packaging). The VeriSight ICE catheter provides 2D ultrasound imaging capabilities. The VeriSight Pro ICE catheter provides 2D and/or 3D ultrasound imaging capabilities, depending on the model and configuration of the EPIQ ultrasound system it connects to. The catheters are compatible with ancillary equipment such as sheaths and introducers. The catheters are sterilized via Ethylene Oxide.

The catheters connect to the Philips EPIQ Diagnostic Ultrasound System via a patient interface module (PIM); the connection between the catheter and the PIM is located outside the sterile field. The catheters will not operate if connected to any other imaging system. These catheters are for exclusive use with Philips EPIQ 7C, CVx, and CVxi series of ultrasound systems, cleared under K202216.

Indications for Use:

VeriSight/ VeriSight Pro ICE catheter:

The VeriSight/ VeriSight Pro ICE catheter is intended for intracardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

Predicate Device Comparison:

Technological Comparison Table:

Comparison of the proposed VeriSight/VeriSight Pro ICE Catheters to the currently marketed predicate device, the AcuNav Diagnostic Ultrasound Catheter 8F, 10F.			
Standard Feature	**VeriSight/VeriSight Pro ICE Catheters K200812 (Proposed Device)**	**AcuNav Diagnostic Ultrasound Catheter K170263 (Predicate Device)**	**ACUSON AcuNav Volume ICE Catheter K173618 (Reference Device)**
Indications for Use	The VeriSight/VeriSight Pro ICE catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.	The catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.	The catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.
Catheter Type	Intracardiac Echocardiography	Intracardiac Echocardiography	Intracardiac Echocardiography
Single-Use	Yes	Yes	Yes
Duration of Use	Limited (≤ 24 hours)	Limited (≤ 24 hours)	Limited (≤ 24 hours)
Scientific Technology	Ultrasound Imaging Frequency	Ultrasound Imaging Frequency	Ultrasound Imaging Frequency
Compatible with Previously-cleared Ultrasound Systems?	Yes	Yes	Yes
Number of	840	64	Unknown

Standard Feature	VeriSight/VeriSight Pro ICE Catheters K200812 (Proposed Device)	AcuNav Diagnostic Ultrasound Catheter K170263 (Predicate Device)	ACUSON AcuNav Volume ICE Catheter K173618 (Reference Device)
Ultrasound Transducer Elements			
Nominal Center Frequency [MHz]	7 MHz	6.5 MHz	Unknown
Operating principles	Catheter with ultrasound sensors that is used with an imaging system to display to provide high-resolution real-time visualization of cardiac structures, continuous monitoring of catheter location within the heart	Catheter with ultrasound sensors that is used with an imaging system to display to provide high-resolution real-time visualization of cardiac structures, continuous monitoring of catheter location within the heart	Catheter with ultrasound sensors that is used with an imaging system to display to provide high-resolution real-time visualization of cardiac structures, continuous monitoring of catheter location within the heart
Image Technique to Visualize Device	Fluoroscopy	Fluoroscopy	Fluoroscopy
Catheter Diameter	9F	8F, 10F	12.5F
Sheath Compatibility	10F	9F, 11F	>12.5F
Catheter Working Length	90cm	90cm	90 cm
Imaging Modes	VeriSight: • 2D (B-Mode) • M-Mode • Pulse wave Doppler • Continuous wave Doppler • Color Doppler VeriSight Pro:	• 2D (B-Mode) • M-Mode • Pulse wave Doppler • Continuous wave Doppler • Color Doppler	• 2D (B-Mode) • M-Mode • Pulse wave Doppler • Continuous wave Doppler • Color Doppler Volume • 3D

Standard Feature	VeriSight/VeriSight Pro ICE Catheters K200812 (Proposed Device)	AcuNav Diagnostic Ultrasound Catheter K170263 (Predicate Device)	ACUSON AcuNav Volume ICE Catheter K173618 (Reference Device)
	• 2D (B-Mode) • M-Mode • Pulse wave Doppler • Continuous wave Doppler • Color Doppler • Live 3D • Live 3D color		
Acoustic Output Track	Track 3	Track 3	Track 3
Safety and EMC Compliance	EN/IEC 60601-1 IEC 60601-2-37 EN/IEC 60601-1-2	IEC 60601-1 IEC 60601-2-37 IEC 60601-1-2	IEC 60601-1 IEC 60601-2-37 IEC 60601-1-2
Accessories	Philips ICE PIM	Sterile Cover, Swiftlink Catheter Connector	Sterile Cover, Swiftlink Catheter Connector

The Technological Comparison Table above provides a detailed comparison demonstrating that both the VeriSight/VeriSight Pro ICE Catheters and the predicate AcuNav Diagnostic Ultrasound Catheter share the same intended use and similar indications for use, same principle of operation for primary function (ultrasonic imaging), the same mechanism of action for achieving actuation, similar physical form of the catheter, and the same clinical operation and the device life cycle (sterile, single use disposable). Hence, the VeriSight/VeriSight Pro ICE Catheters are substantially equivalent to the predicate device, the Siemens AcuNav Diagnostic Ultrasound Catheter 8F, 10F cleared under K170263.

Any differences between the subject and predicate devices were evaluated through design verification and validation testing, which did not raise new questions of safety and/or effectiveness and support a determination of substantial equivalence.

Reference Device Comparison:

The ACUSON AcuNav Volume ICE Catheter (K173618), is identified as a reference device and shares the same operating principles and technological characteristics, specifically when related to Philips VeriSight Pro ICE catheter's 3D imaging modalities.

Summary of Non-Clinical Performance Testing:

The VeriSight/VeriSight Pro ICE Catheters have been evaluated for performance and technological characteristics by completion of the following design verification and validation tests:

- Visual inspection
- Dimensional
- Actuation characteristics
- Tip deflection
- Torsional shaft
- Tensile tests
- Deliverability
- Saline imaging
- Particulate
- Usability
- Preclinical Animal testing
- Biocompatibility
- Sterilization
- Packaging and Shelf Life Validation
- System testing with EPIQ System
- Electrical Safety, EMC and acoustic output testing with EPIQ System

The VeriSight and VeriSight Pro Catheters comply with the following voluntary standards for Electrical Safety, EMC and Acoustic Outputs:

- Electrical Safety and EMC Requirements for Medical Equipment
  - EN IEC 60601-1
  - EN IEC 60601-1-2
- EN IEC 60601-2-37, Diagnostic Ultrasound Safety Standards
- IEC 62359, Ultrasonics - Field characterization

Summary of Clinical Performance Testing:

The VeriSight/VeriSight Pro ICE catheters use the same scientific technology, operating principles and shares similar indications for use as the predicate device. Therefore, clinical data is not required to establish substantial equivalence.

Conclusion:

The VeriSight/VeriSight Pro ICE catheters, when connected to the EPIQ Diagnostic Ultrasound System, use the same scientific technology, operating principles and indications for use as the predicate device. Based on results of non-clinical testing, and the information submitted in this 510(k) Premarket Notification, the subject VeriSight/VeriSight Pro ICE Catheters are substantially equivalent to currently marketed devices.