May 9, 2025

Philips Image Guided Therapy Corporation
Travis Pittman
Head of Regulatory - Cardiac Solutions
3721 Valley Centre Drive, Suite 500
San Diego, California 92130

Re: K251103
Trade/Device Name: VeriSight Intracardiac Echocardiography Catheter (VSICE2D);
VeriSight Pro Intracardiac Echocardiography Catheter (VSICE3D)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: April 10, 2025
Received: April 11, 2025

Dear Travis Pittman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 S. Deoras -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251103

Device Name

VeriSight Intracardiac Echocardiography Catheter (VSICE2D);
VeriSight Pro Intracardiac Echocardiography Catheter (VSICE3D)

Indications for Use *(Describe)*

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 of adult and pediatric patients. 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Submitter Information:

Date Prepared	May 08, 2025
Manufacturer Name and Address	Philips Image Guided Therapy Corporation 3721 Valley Centre Drive, Suite 500 San Diego, CA 92130 USA
Est. Registration Number	3008363989
Primary Contact Information	Travis Pittman Head of Regulatory Affairs CS TEL: +1(719) 447-2470 EMAIL: travis.pittman@philips.com
Secondary Contact	Matt Im Senior Regulatory Affairs Specialist EMAIL: matt.im@philips.com

Subject Device Information:

Trade Name	VeriSight Intracardiac Echocardiography Catheter (VSICE2D), VeriSight Pro Intracardiac Echocardiography Catheter (VSICE3D)
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: K200812 – VeriSight/VeriSight Pro ICE Catheters
Reference Device: K170263 AcuNav Diagnostic Ultrasound Catheter

Subject Device Description:

The purpose of this submission is solely to add pediatric indications to the VeriSight/VeriSight Pro ICE Catheters (Cleared under K200812).

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.

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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:

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 of adult and pediatric patients. The catheter is intended for imaging guidance only, not treatment delivery, during cardiac interventional percutaneous procedures.

Predicate Device Comparison:

The subject VeriSight/VeriSight Pro ICE catheters are identical to the current cleared VeriSight/Verisight Pro ICE catheters (cleared under K200812). The only difference is the updated indications to add a pediatric indication as in the reference device (K170263).

Sterility testing from the cited predicate was used to determine the weight thresholds below which pediatric patients may be exposed to harmful levels of ethylene oxide and ethylene chlorohydrin. The Instructions for Use for the device are appropriately modified to warn users that exceeding the calculated weight threshold may lead to exposure of the patient to harmful levels of ethylene oxide and ethylene chlorohydrin.

The addition of pediatric indications to the VeriSight/VeriSight Pro ICE Catheters did not raise new questions of safety and/or effectiveness and support a determination of substantial equivalence to the currently cleared VeriSight/VeriSight Pro ICE catheters.

Summary of Non-Clinical Performance Testing:

The purpose of this submission is solely to add pediatric indications to the currently cleared VeriSight/VeriSight Pro ICE catheters (cleared under K200812). No additional non-clinical performance testing was executed for this change.

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.

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Conclusion:

The VeriSight/VeriSight Pro ICE catheters use the same scientific technology, operating principles and indications for use as the predicate device. Based on the technological comparison and the information submitted in this 510(k) Premarket Notification, the subject VeriSight/VeriSight Pro ICE Catheters are substantially equivalent to currently marketed devices.