Philips Medical Systems Nederland B.V.
% Supriya Dalvi
Regulatory Affairs Specialist
Veenpluis 6
Best, 5684 PC
NETHERLANDS

May 31, 2022

Re: K221270
Trade/Device Name: EchoNavigator R4.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 26, 2022
Received: May 2, 2022

Dear Supriya Dalvi:

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,

Jessica Lamb
Assistant Director
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of Radiological Health
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)*
K221270

Device Name
EchoNavigator R4.0

Indications for Use *(Describe)*
EchoNavigator supports the interventionalist and surgeon in treatments where both live X-ray and live Echo guidance are used. The targeted patient population consists of patients with cardiovascular diseases requiring such a treatment

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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K221270

510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared:	April 26th, 2022	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 6, 5684 PC Best The Netherlands Establishment Registration Number: 3003768277	
Primary Contact Person:	Dr. Supriya A. Dalvi Regulatory Affairs Specialist, IGT Systems Phone: +31 628945536 E-mail: supriya.dalvi@philips.com	
Device:	Trade Name:	**EchoNavigator**
	Release Name:	R4.0
	Classification Name:	Picture archiving and communications system
	Classification Regulation:	21 CFR, Part 892.2050
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	LLZ
Predicate Device:	Trade Name:	*EchoNavigator R3.0.3*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K200713 (April 9th, 2020)
	Classification Name:	Picture archiving and communications system
	Classification Regulation:	21 CFR, Part 892.2050
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	LLZ

Device description: **EchoNavigator R4.0** is a tool that assists the interventionalist and surgeon with image guidance during treatment of cardiovascular disease for which the procedure uses both live X-ray and live Echo guidance. EchoNavigator can be used with compatible Echo-probes and Echo units in combination with compatible Philips interventional X-ray systems.

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Indications for Use:

EchoNavigator supports the interventionalist and surgeon in treatments where both live X-ray and live Echo guidance are used. The targeted patient population consists of patients with cardiovascular diseases requiring such a treatment.

Technological characteristics:

The subject device, **EchoNavigator R4.0**, has the same fundamental scientific technology as the predicate device (*EchoNavigator R3.0.3*, K200713).

The subject and predicate devices are based on the following *same technological characteristics:*

- The ability of the subject device to display images from the live X-ray and Ultrasound modalities and the *core algorithm for probe (transducer) detection* is fundamentally unchanged compared to the predicate device.
- The following functionalities are available in both predicate and subject device: *Synchronize Image Orientation, Multiple Views, Follow C-arm, Table Side Control, Mannual Annotations* and *Image Capture Export.*

The following modifications were implemented in subject device, **EchoNavigator R4.0**:

- In addition to the existing workspots, the subject device has introduced the Echonavigator functionality on the touch screen user interface of the Echo console. The user interface functions of subject device are same as those for the predicate device (*EchoNavigator R3.0.3*, K200713). This additional user interface has exactly the same functions as the existing workspots.
- In the subject device, automatic annotations can be used to automatically align the 3D echo volume and the MPR planes with the position of these automatic annotations (called 'AutoViews'). In the predicate device (*EchoNavigator R3.0.3*, K200713), the automatic annotations were already present, however, positioning of 3D echo volume and the MPR planes was done manually. The automatic annotations functionality is fundamentally unchanged in subject device compared to predicate device (*EchoNavigator R3.0.3*, K200713).
- Minor updates to the existing 3D heart model (Adding mitral valve leaflets and transseptal zone area). These are solely intended to be used by the user as context information for the patient's anatomy. These changes are not fundamental changes to the technological characteristics of automatic annotations.
- Rendering modes like the MPR visualisation, TrueVue and GlassVue are updated in the subject device to support the rendering modes introduced in recent releases of Echo console.

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The outcome of this technological characteristics comparison and risk assessment demonstrate that the minor differences in the technological characteristics do not affect the safety or effectiveness of the subject device, **EchoNavigator R4.0**, when compared to the legally marketed predicate device (*EchoNavigator R3.0.3*, K200713). Thus demonstrating the substantial equivalence of the subject device with the predicate device.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the subject device, **EchoNavigator R4.0**, and it demonstrates compliance with the following FDA-recognized consensus standards and guidance documents:

- IEC 62304 Edition 1.1 2015-06. Medical device software - Software life cycle processes. *FDA recognition number 13-79*
- IEC 62366-1 Edition 1.1 2020-06. Medical devices - Part 1: Application of usability engineering to medical devices. *FDA recognition number 5-129*
- IEC 82304-1 Edition 1.0 2016-10. Health software – Part 1: General requirements for product safety. *FDA recognition number 13-97*
- ISO 14971 Third Edition 2019-12. Medical devices – Application of risk management to medical devices. *FDA recognition number 5-125*
- ISO 15223-1 Third Edition 2016-11-01. Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirement. *FDA recognition number 5-117*
- ANSI UL 2900-1 First Edition 2017. Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements. *FDA recognition number 13-96*
- IEC 80001-1 Edition 1.0 2010-10. Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities. *FDA recognition number 13-38*. (Compliance to the medical device requirements of IEC 80001-1:2010, Edition 1.0 are applicable and followed by EchoNavigator)
- *"Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"*, May 11, 2005
- *"Guidance for Industry and FDA Staff - Applying Human Factors and Usability Engineering to Medical Devices"*, February 3, 2016
- *"Guidance for Industry and FDA Staff – Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"*, October 2, 2014
- *"Guidance for Industry and FDA Staff – The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]"*, July 28, 2014

Software verification testing has been performed on the subject device, **EchoNavigator R4.0**, to verify that all System Requirements Specification

including all the Privacy and Security requirements have been implemented. Results demonstrated that all executed verification tests were passed.

Non-clinical in-house simulated use design validation testing has been performed to validate that the subject device, **EchoNavigator R4.0**, conforms to intended use, claims and user needs. Results demonstrated that all executed validation testing passed as per the test protocols.

Non-clinical verification and validation test results demonstrate that the subject device, **EchoNavigator R4.0**:

- Complies with the aforementioned FDA recognized consensus standards and guidance documents.
- Meets the acceptance criteria and is adequate for its intended use.

The subject device, **EchoNavigator R4.0** did not require clinical study since substantial equivalence to the predicate device (*EchoNavigator R3.0.3*, K200713) was demonstrated in terms of the indication for use; technological characteristics; non-clinical performance testing; and safety and effectiveness.

Substantial Equivalence Conclusion:

The subject device, **EchoNavigator R4.0**, is substantially equivalent to the predicate device (*EchoNavigator R3.0.3,* K200713), in terms of indications for use, technological characteristics, safety and effectiveness.

Additionally, substantial equivalence was demonstrated by non-clinical performance tests provided in this 510(k) premarket notification. These tests demonstrate that subject device, **EchoNavigator R4.0**, complies with the user need requirements as well as the requirements specified in the FDA-recognized consensus standards and guidance documents.

Therefore, the subject device, **EchoNavigator R4.0**, is as safe and effective as the predicate device (*EchoNavigator R3.0.3,* K200713) and does not raise any new safety and/or effectiveness concerns.