Philips Medical Systems Nederland B.V.
℅ Ioana Ulea
Regulatory Affairs Specialist
Veenpluis 6
5684 PC Best
THE NETHERLANDS

April 9, 2020

Re: K200713
Trade/Device Name: EchoNavigator R.3.0.3
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 16, 2020
Received: March 18, 2020

Dear Ioana Ulea:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200713

Device Name
EchoNavigator R3.0.3

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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510(k) Summary

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

Date Prepared:	March 16th, 2020	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 6, 5684 PC Best The Netherlands Establishment Registration Number: 3003768277	
Primary Contact Person:	Ioana Ulea Regulatory Affairs Specialist, IGT Systems Phone: +31 618345875 E-mail: ioana.ulea@philips.com	
Secondary Contact Person:	Michael Konings Director Regulatory Affairs IGT Systems Phone: +31 619864032 E-mail: michael.konings@philips.com	
Device:	Trade Name:	**EchoNavigator**
	Release Name:	R3.0.3
	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 R1*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K121781 (October 26, 2012)
	Classification Name:	Picture archiving and communications system
	Classification Regulation:	21 CFR, Part 892.2050
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	LLZ

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Reference Device:	Trade Name:	QLAB Advanced Quantification Software
	Manufacturer:	Philips Ultrasound, Inc.
	510(k) Clearance:	K181264
	Classification Name:	Picture archiving and communications system
	Classification Regulation:	21 CFR 892.2050
	Classifcation Panel:	Radiology
	Device Class:	Class II
	Product Code:	LLZ

Device description:

EchoNavigator 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.

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 proposed **EchoNavigator R3.0.3** has similar technological characteristics compared to the predicate device.

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

- The ability of the proposed 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 proposed device: *Synchronize Image Orientation, Multiple Views, Follow C-arm, Table Side Control, Mannual Annotations* and *Image Capture Export.*

The following modifications were implemented in **EchoNavigator R3.0.3:**

- The *Multiple Views* functionality provided by the predicate device is extended in the proposed device with the *Model View*, which is an additional view compared to the Multiple Views available in the predicate device (X-ray, Free, Echo and C-arm).
- Although the Table Side Control is available in both devices, the proposed device offers basic control from the Touch Screen Module (TSM) in addition to the wireless mouse control on the tray table, as offered by the predicate device.
- While both devices are allowing the user to identify anatomical structures in one modality and annotate them by *Mannual*

Annotations, the proposed device extends this functionality with *Automatic Annotations*. This functionality is allowing the user to identify anatomical structures in the echo modality and annotate them with annotations and tissue contours as proposed by the device.

- While the predicate device can be controlled only in the control room or in the exam room by using a table side mouse (wireless mouse on a tray mounted to the table at the foot side of the patient), the proposed device also allows *control from the Echo console.*

The differences between the proposed and the predicate device do not raise any new questions regarding safety or effectiveness. Based on the information provided in this 510(k) submission, **EchoNavigator R3.0.3** is considered substantially equivalent to the predicate *EchoNavigator R1* in terms of fundamental scientific technology.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the EchoNavigator R3.0.3 and demonstrates compliance with the following International and FDA-recognized consensus standards:

No#	Standard Number and Date	Standard Name	Recognition Number
1.	IEC 62304 Edition 1.1 2015-06	Medical device software – Software life cycle processes	13-79
2.	IEC 62366-1 Edition 1.0 2015-02	Medical devices – Part 1: Application of usability engineering to medical devices	5-114
3.	IEC 82304-1 Edition 1.0 2016-10	Health software – Part 1: General requirements for product safety	13-97
4.	ISO 14971:2007/ (R)2010 (Corrected 4 October 2007)	Medical devices – Application of risk management to medical devices	5-40
5.	ISO 15223-1 Third Edition 2016-11-01	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied	5-117
6.	UL 2900-1 First Edition 2017	Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements	13-96
7.	IEC 80001-1 Edition 1.0 2010-10	Application of risk management for IT-networks incorporating	13-38

		medical devices – Part 1: Roles, responsibilities and activities	

Software verification testing has been performed 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. Software Verification data supports the proposed **EchoNavigator R3.0.3** relative to the predicate *EchoNavigator R1*.

Non-clinical in-house simulated use design validation testing has been performed to validate that EchoNavigator R3.0.3 conforms to intended use, claims and user needs. Results demonstrated that all executed validation protocols were passed.

Summary of Clinical Performance Data:

The EchoNavigator R3.0.3 introduces no new indications for use or technological characteristics relative to predicate device (K121781) that would require clinical testing.

Substantial Equivalence Conclusion:

The **EchoNavigator R3.0.3** is substantially equivalent to the predicate device *EchoNavigator R1* 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 **EchoNavigator R3.0.3** complies with the user need requirements as well as the requirements specified in the FDA-recognized consensus standards and guidance documents.

Therefore **EchoNavigator R3.0.3** is as safe and effective as its predicate device and does not raise any new safety and/or effectiveness concerns.