March 17, 2026

Philips Medical Systems Nederland B.V
Yesheshvi Anush Puvvada
Principal Regulatory Affairs Specialist
Veenpluis 6
5684 Pc
Best, Netherlands

Re: K253614
Trade/Device Name: EchoNavigator R5.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: February 17, 2026
Received: February 17, 2026

Dear Yesheshvi Anush Puvvada:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

for

Jessica Lamb, Ph.D.
Assistant Director, Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253614

Please provide the device trade name(s).

EchoNavigator R5.0

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

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

Date Prepared: **March 16, 2026**

Manufacturer:
Philips Medical Systems Nederland B.V.
Veenpluis 6
5684 PC Best
The Netherlands
Establishment Registration Number: 3003768277 (Please note that this is the new establishment registration number that got assigned on December 21st, 2025. The old establishment registration number was 3003768277 which was used during the initial 510(k) application submission. This is an administrative registration update only. There are no changes in ownership, legal entity name, address, or any product related technical changes.)

Primary Contact Person:
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Device:

Trade Name:	**EchoNavigator R5.0**
Classification Name:	Medical image management and processing system.
Classification Regulation:	21CFR §892.2050
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	Primary Code: QIH Associated Product Code: LLZ

Predicate Device:

Trade Name:	*EchoNavigator R4.0*
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K221270 (cleared on 31 May 2022)
Classification Name:	Medical image management and processing system
Classification Regulation:	21CFR §892.2050

Classification Panel:	Radiology
Device Class:	Class II
Product Code:	Primary Code: LLZ

Device description:

EchoNavigator is a Software Medical Device 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 subject and predicate devices are based on the same technological characteristics:
EchoNavigator's operating principle is receiving live X-ray images from an existing X-ray system and live Echo images from an existing Ultrasound system. Based on the X-ray images, the position of the Echo probe with respect to the X-ray system is determined through a software algorithm. Based on the probe position the live Echo images or parts thereof are displayed simultaneously with the X-ray images, either side-by-side or fused. The device is user controlled by standard human input devices. EchoNavigator can simultaneously provide output on the primary display of the X-ray system and on the displays of the EPIQ ultrasound system.

In the subject device, EchoNavigator R5.0, the following changes are being implemented. (**Table 1**).

Table 1: Overview of the changes for EchoNavigator R5.0

Change Number	Feature/Change	Change and Rationale for change
1.	Addition of a new function in EchoNavigator R5.0: M-TEER device detection (also known as device tracking) and overlay DeviceGuide functionality	Mitral Transcatheter Edge-to-Edge Repair (M–TEER) device detection and overlay involves detecting the location of the M-TEER therapy device in the X-ray and echo images (enabled by Artificial Intelligence). The TEER device detection and overlay function has the following optional features: • visualization of the shape, trajectory, and orientation of mitral TEER device overlaid on X-ray and/or echo images. • device focused echo views (on the TEER device) to optimize the visualization of the relationship between device and surrounding anatomy. The software element of this functionality

		contains the algorithms to detect/track the location and orientation of M-TEER therapy devices (this release only supports Edwards' PASCAL Ace M-TEER therapy device). • *Input:* 2D X-ray image + geometry information + 3D echo volume + TEE probe registration result. • *Output:* 3D position, orientation and openness angle of therapy device, including detection status. The intent of this function is to assist physicians in device guidance and navigation when performing TEER procedures. This is an -on demand function for the physician. Please note that all the other features and the underlying algorithms of EchoNavigator R5.0 are the same as the features and underlying algorithms of the predicate device. (EchoNavigator R4.0, K221270)
2.	UI Harmonization	Harmonization of the EchoNavigator UI with the UI offered on the EPIQ system (Ultrasound console): • Harmonize the presentation of echo views offered in EchoNavigator with those offered on the EPIQ system, such that there are minimal differences between the echo views when the user switches between EPIQ system and EchoNavigator views. • Harmonize buttons and button presentation, bringing it in line with the EPIQ system.
3.	Proposed Product Claims	The proposed product claims for EchoNavigator R5.0 (which are new in comparison to the predicate device, (EchoNavigator R4.0, K221270)) are as follows: • Automated visualization of trajectory and orientation of mitral TEER device • Improved imaging workflow through a dedicated user interface for Mitral TEER. • Automatic device augmentation on echo (Augmented Reality) • DeviceGuide offers real-time automatic device detection, tracking and 3D pose-estimation in live Echo and live X-ray enabled by Artificial Intelligence which is built with Deep Learning technology.

		• DeviceGuide is an on-demand functionality for the interventional imager (e.g. echo cardiologist) and/or the interventional operator (e.g. interventional cardiologist) • Automatic device focused view (on the mitral TEER device) to optimize the visualization of the relationship between device and surrounding anatomy. • DeviceGuide enables identification, positioning, trajectory guidance, and orientation visualization during M-TEER procedures, supporting effective navigation.

EchoNavigator R5.0 (Subject Device) Features

Features of the proposed subject device, EchoNavigator R5.0 are:

- **Synchronize Image Orientation**
  Giving procedural-relevant context to the live X-ray and Echo data by:
  - Automatically synchronizing the image orientation of both modalities (by use of the "Orientation Indicator"), as opposed to relying solely on the Echo-operator to create this context manually.
  - Automatically aligning the Echo views (including MPRs) to a clinically relevant orientation after the user selects the required anatomical preset (so called AutoViews) or based upon the position of the therapy device.

- **Multiple Views**
  Allowing the visualization of relevant anatomical structures in the live Echo data in multiple simultaneous user defined views.

- **Follow C-arm**
  Automatically presenting the Echo data in the same orientation as the live X-ray images from the X-ray system, as opposed to relying on the Echo-operator to provide this orientation.

- **Table Side Control**
  Allowing the X-ray user to interrogate the relevant anatomical structures in the Echo data from table side, as opposed to requesting the Echo-operator to perform the interrogation.

- **Ultrasound Side Control**
  Allowing the Echo user to control the relevant functionality for fusion image of Echo and X-ray from the Ultrasound system.

- **Annotations (Manually Placed on either X-ray or Echo)**
  Allowing the user to identify anatomical structures in one modality and

annotate them manually with annotations. These annotations are automatically transposed to the other modality. The annotations are visualized in all selected views and are solely intended to be used as context information to help the user with the navigation of the catheter and the therapy device in the patient's anatomy.

- **Annotations (Placed on Echo)**
  Allowing the user to identify anatomical structures in the Echo modality and annotate them with annotations and tissue contours as proposed by the device. These annotations are automatically transposed to the X-ray modality. The annotations are visualized in all selected views and are solely intended to be used as context information to help the user with the navigation of the catheter and the therapy device in the patient's anatomy.

- **Overlay on X-Ray**
  Project the Echo image or volume as overlay or only as outline on top of the X-ray view.

- **X-Ray On Echo**
  Allowing the Echo operator to view and annotate the X-ray image from the Echo console.

- **Therapy Device Detection (Also known as the DeviceGuide functionality/feature)**
  Project the shape, trajectory, and orientation of the therapy device as overlay on top of the X-ray view and/or in the Echo view. Provide TEER therapy device focused echo views to optimize the visualization of the relationship between device and surrounding anatomy.
  This is the only new feature of EchoNavigator R5.0 in comparison to EchoNavigator R4.0.

Summary of Non- Clinical Performance Data:

Non-clinical performance testing has been performed on the subject device, EchoNavigator R5.0 and it demonstrates compliance with the following FDA recognized consensus standards:

- IEC 62304 Medical device software – Software life cycle processes (Edition 1.1, 2015-06 Consolidated Version). FDA/CDRH recognition number 13-79.
- IEC 62366-1 Medical devices - Part 1: Application of usability engineering to medical devices (Edition 1.1, 2020-06 Consolidated Version). FDA/CDRH recognition number 5-129.
- IEC 82304-1 Health software – Part 1: General requirements for product safety (Edition 1.0 2016-10), FDA/CDRH recognition number 13-97.
- ISO 14971 Medical devices – Application of risk management to medical devices (Third Edition 2019-12). FDA/CDRH recognition number 5-125.
- ISO 15223-1 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (Fourth edition 2021-07). FDA/CDRH recognition number 5-134.
- ISO 20417:2021 Medical devices — Information to be supplied by the

manufacturer (First edition 2021-04 Corrected version 2021-12). FDA/CDRH recognition number 5-135.

- UL ANSI 2900-1, Standard For Safety, Standard For Software Cybersecurity Network-Connectable Products, Part 1: General Requirements (First Edition, 2017). FDA/CDRH recognition number 13-96
- UL ANSI 2900-2-1, Standard for Safety Software Cybersecurity for Network-Connectable Products Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems, (First Edition, 2017). FDA/CDRH recognition number 13-104
- IEC 81001-5-1 Edition 1.0 2021-12 Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle. FDA/CDRH recognition number 13-122.
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], issued July 28, 2014 (Document number 1766).
- Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff, June 14, 2023 (Document number GUI00000337).
- Guidance for Industry and FDA Staff - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, June 27, 2025. (Document number GUI00001825).
- Guidance for Industry, and Food and Drug Administration Staff - Off-The-Shelf Software Use in Medical Devices", August 11, 2023 (document number GUI00000585).
- Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations Draft Guidance for Industry and Food and Drug Administration Staff - Draft Guidance issued on January 7, 2025. (document number GUI00007028).
- Postmarket Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff, December 28, 2016. (document number 1400044).
- Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016 (document number 1757).

Software verification testing of the functional and non-functional requirements as well as performance, reliability and safety testing has been successfully performed to verify that all the requirements of Product Requirements Specification as well as the safety risk control measures from the Detailed Risk Management Matrix and the Privacy and Security requirements and mitigations have been implemented. Results demonstrated that all executed tests were passed.

Non-clinical validation testing has been performed to validate that **EchoNavigator R5.0** conforms to the intended use, claims, user needs, effectiveness of safety measures and instructions for use.

The subject device, **EchoNavigator R5.0** did not require a clinical study since substantial equivalence to the predicate device (EchoNavigator R4.0, K221270) was demonstrated in terms of the indication for use; technological characteristics; non-clinical performance testing; and safety and effectiveness.

DeviceGuide uses an AI algorithm that was verified and validated using procedural image data from 72 unique patients. In addition, image data from 41 patients were used for out-of-domain testing. Data were sourced from a diverse mix of institutions (academic centers and community hospitals) across the U.S. and Europe. Clinical data were acquired using a range of compatible Philips X-ray and Philips ultrasound systems under routine procedural conditions. To ensure independence between development and testing, testing was performed after algorithm development was completed and the algorithm was frozen. Data used for development were not used for testing. To support representative evaluation across intended-use settings, the validation dataset included at least 50% U.S. site data.

Verification included element-level testing against manually annotated images and assessment of algorithm outputs against predefined acceptance criteria. In addition, algorithm outputs were compared to a reference standard ("ground truth") derived from pre-clinical high resolution imaging data. Performance was quantified as error versus the reference standard and compared against predefined acceptance criteria. Overall performance met predefined specification limits, including ≤5 mm positional accuracy and ≤10° trajectory/orientation accuracy. Algorithm latency met predefined specification, including detection and localization of the therapy device within 100ms of reception of the echo image. In a clinical review, five physicians assessed the algorithm output as sufficient in 93.1% of evaluated cases.

All these tests were used to support substantial equivalence of the subject device and demonstrate that **EchoNavigator R5.0**:

- complies with the international and FDA-recognized consensus standards, and
- meets the acceptance criteria and is adequate for its intended use.

Therefore, the subject device **EchoNavigator R5.0** is substantially equivalent to the predicate device EchoNavigator R4.0 in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The proposed **EchoNavigator R5.0** did not require a clinical study since substantial equivalence to the currently marketed and predicate device EchoNavigator R4.0 was demonstrated with the following attributes:

- Indications for use;
- Technological characteristics;
- Non-clinical performance testing; and
- Safety and effectiveness.

Substantial Equivalence Conclusion:

The subject device, **EchoNavigator R5.0**, is substantially equivalent to the predicate device (EchoNavigator R4.0, K221270), in terms of indications for use, technological characteristics, and 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 R5.0**, 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 R5.0**, is as safe and effective as the predicate device (EchoNavigator R4.0, K221270) and does not raise any new safety and/or effectiveness concerns