DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Philips Medical Systems Nederland B.V.
% Ms. Liselotte Kornmann
Regulatory Affairs Manager
Veenpluis 4-6
Best, 5684 PC
Netherlands

December 9, 2014

Re: K142126
Trade/Device Name: EP Navigator rel. 5.0
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, LLZ
Dated: November 14, 2014
Received: November 17, 2014

Dear Ms. Kornmann:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142126

Device Name

EP navigator

Indications for Use *(Describe)*

EP navigator is intended to provide navigation support for cardiovascular devices for heart rhythm disorders, such as catheters and guidewires, by superimposing 3D cardiac anatomical image data, such as CT, MRI, or 3D rotational scan over intra-procedural X-ray images of the same anatomy.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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PHILIPS

510(k) Summary of Safety and Effectiveness

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

Date Prepared:	July 31, 2014	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684 PC Best The Netherlands Establishment Registration Number: 3003768277	
Contact Person:	Ms. Liselotte Kornmann, PhD Regulatory Affairs Manager Phone: +31 611621238 E-mail: Liselotte.Kornmann@philips.com	
Device:	Trade Name:	**EP navigator Rel. 5.0**
	Common Name:	**EP navigator**
	Device Class:	Class II
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	Radiology
	Primary Product Code:	OWB (Interventional x-ray system)
	Secondary Product Code:	LLZ (system, image processing, radiological)
Primary[1] Predicate Device:	Trade Name:	Allura Xper FD series Allura Xper OR Table series
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K133292 (March 05, 2014)
	Classification Regulation:	21 CFR, Part 892.1650
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	OWB (primary), JAA (secondary)

[1] Note: the **EP navigator Rel. 5.0** software medical device is an accessory to the currently marketed and primary predicate Allura Xper FD series and Allura Xper OR Table series K133292. The Allura Xper FD series and Allura Xper OR Table series will be abbreviated as Allura X-ray system in this 510(k) Pre-market notification. Substantial equivalence demonstration to the primary predicate is not warranted as they are devices with which **EP navigator Rel. 5.0** is to be used. Therefore, substantial equivalence is demonstrated to the secondary predicate devices.

Secondary Predicate Devices #1:	Trade Name:	EP navigator Rel. 3.0
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K101311 (Sep 30, 2010)
	Classification Regulation:	21 CFR, Part 892.2050
	Classification Name:	Picture Archiving and Communications System
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	LLZ
Secondary Predicate Devices #2:	Trade Name:	HeartNavigator Rel. 2.0
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K140138 (June 10, 2014)
	Classification Regulation:	21 CFR, Part 892.1650
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	OWB, LLZ

Device Description: **EP navigator Rel. 5.0** is a software medical device that contains image processing algorithms that are executed on a PC-based hardware platform. **EP navigator Rel. 5.0** can perform the following functions:

- view previously acquired 3D anatomical image data in a slice viewer, such as CT, MRI, or 3D rotational scan,
- segment previously acquired 3D anatomical image data,
- register the segmented 3D dataset and landmarks with intra-procedural X-ray images,
- superimpose the segmented 3D dataset and landmarks on intra-procedural X-ray images of the same anatomy,
- position visual markers such as tag points, and
- visualize the inside of the 3D volume (EndoView).

Indications for Use: EP navigator is intended to provide navigation support for cardiovascular devices for heart rhythm disorders, such as catheters and guidewires, by superimposing 3D cardiac anatomical image data, such as CT, MRI, or 3D rotational scan over intra-procedural X-ray images of the same anatomy.

Fundamental Scientific Technology: **EP navigator Rel. 5.0** is intended to be used in combination with the primary predicate device Allura X-ray system (K133292). While the secondary predicate device EP navigator Rel. 3.0 (K101311) and **EP navigator Rel. 5.0** share the same technological characteristics, **EP navigator Rel. 5.0** offers the following enhancements to existing functions: (1) Support of the import and automatic segmentation of MR datasets, (2) Reduced angular range of 3D EP rotational scan and support of the automatic segmentation of a 3D EP rotational scan with reduced angular angle, (3) Manual 2D measurements, (4) Anatomical-based viewing planes, and (5) Communication with Philips X-ray system, including Automatic Position Control (APC). The modifications represented by **EP navigator Rel. 5.0** do not affect the safety and effectiveness of the device.

Therefore, **EP navigator Rel. 5.0** is substantially equivalent to the currently marketed and secondary predicate EP navigator Rel. 3.0 (K101311) and HeartNavigator Rel. 2.0 (K140138) in terms of fundamental scientific technology.

Summary of Non-clinical Performance Data:

Non-clinical performance testing has been performed on **EP navigator Rel. 5.0** and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- IEC 62304 Medical device software – Software life cycle processes (Ed. 1.0, 2006),
- IEC 62366 Medical devices – Application of usability engineering to medical devices (Ed. 1.0, 2007),
- ISO 14971 Medical devices – Application of risk management to medical devices (Ed. 2.0, corrected version, 2007),
- NEMA PS 3.1-3.20 Digital Imaging and Communications in Medicine (DICOM) Set (2011), and
- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2005, document number 337).

Verification and validation tests have been performed to address intended use, the technical claims, requirement specifications and the risk management results. The modifications of the EP navigator Rel. 5.0 that are required to implement the enhancements are within the design controls and specifications; a system verification test was performed to ensure that the modifications are properly introduced; verification and validation testing was conducted to ensure the proper introduction of the individual modifications listed; sample clinical images as well as conformance to IEC standards and guidance documents were provided. All of these components and tests were used to support substantial equivalence of the subject device.

The test results in this 510(k) premarket notification demonstrate that **EP navigator Rel. 5.0** complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance document, meets the acceptance criteria, and is adequate for its intended use. Additionally, all risks are sufficiently mitigated, no new risks are introduced and the overall residual risk is acceptable.

Therefore, **EP navigator Rel. 5.0** is substantially equivalent to the currently marketed and secondary predicate devices EP navigator Rel. 3.0 (K101311) and HeartNavigator Rel. 2.0 (K140138) in terms of safety and effectiveness.

Summary of Clinical Data:

EP navigator Rel. 5.0 did not require clinical studies to demonstrate substantial equivalence to the currently marketed and secondary predicate devices EP navigator Rel. 3.0 (K101311) and HeartNavigator Rel. 2.0 (K140138).

Substantial Equivalence Conclusion:

The **EP navigator Rel. 5.0** software medical device is substantially equivalent to the currently marketed and secondary predicate devices EP navigator Rel. 3.0 (K101311) and HeartNavigator Rel. 2.0 (K140138) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, substantial equivalence was demonstrated with non-clinical performance testing, which complied with the requirements specified in

the international and FDA-recognized consensus standards. The non-clinical performance tests provided in this 510(k) premarket notification demonstrates that the proposed **EP navigator Rel. 5.0** is as safe and effective as its predicate devices without raising any new safety and/or effectiveness concerns.