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.
% Liselotte Kornmann, Ph.D.
Regulatory Affairs Manager
Veenpluis 4-6
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THE NETHERLANDS

August 17, 2015

Re: K151598
Trade/Device Name: VesselNavigator
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, LLZ
Dated: May 18, 2015
Received: June 12, 2015

Dear Dr. 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,

For

Robert Ochs, Ph.D.
Acting 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)*

K151598

Device Name

VesselNavigator

Indications for Use *(Describe)*

VesselNavigator provides image guidance by superimposing live fluoroscopic images on a 3D volume of the vessel anatomy to assist in catheter maneuvering and device placement.

VesselNavigator is intended to assist in the treatment of endovascular diseases during procedures such as (but not limited to) AAA, TAA, carotid stenting, iliac interventions.

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.

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5 510(k) Summary of Safety and Effectiveness

510(k) summary

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

Date Prepared: June 9, 2015

Manufacturer:
Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC Best
The Netherlands
Establishment Registration Number: 3003768277

Contact Person:
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E-mail: Liselotte.Kornmann@philips.com

Device:	Trade Name:	**VesselNavigator**
	Device Name:	**VesselNavigator**
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product Code:	OWB (Interventional x-ray system)
	Secondary Product Code:	LLZ (system, image processing, radiological),
Primary Predicate Device:	Trade Name:	*MR-CT Roadmap Rel. 1*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K121772 (March 21, 2013)
	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), JAK, LLZ (secondary)
Reference Device:	Trade Name:	*HeartNavigator Release 2*
	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 (primary), LLZ (secondary)

Device description: VesselNavigator is a software product (Interventional Tool) intended to assist in the treatment of endovascular diseases during an endovascular intervention procedure. VesselNavigator is intended to be used in combination with a Philips Interventional X-ray system. VesselNavigator can be used during any endovascular intervention and covers all vascular anatomy except coronaries and intracranial vessels.

It provides live 3D image guidance for navigating endovascular devices through intended vascular structures in the body, reusing previously acquired diagnostic 3D images. After registration, the 3D volume can be used as a 3D roadmap for navigation; live 2D fluoroscopic images will be overlaid on the 3D volume. In addition, VesselNavigator provides tools to segment the relevant vasculature in the 3D volume (where the end-user is able to edit the segmentation results), place landmarks for easy recognition of key anatomical points of interests, and store and recall of preferred view angles.

Indications for Use: *VesselNavigator provides image guidance by superimposing live fluoroscopic images on a 3D volume of the vessel anatomy to assist in catheter maneuvering and device placement.*

VesselNavigator is intended to assist in the treatment of endovascular diseases during procedures such as (but not limited to) AAA, TAA, carotid stenting, iliac interventions.

The Indications for Use statement for **VesselNavigator** is not identical to the predicate device; compared to *MR-CT Roadmap*, **VesselNavigator** is intended to assist in the treatment of endovascular diseases during procedures. However, this difference does not alter the intended use of the device nor does it affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate device have the same intended use, by superimposing live fluoroscopic images on a 3D volume of the vessel anatomy and are accessories to the Allura Xper X-ray system (K133292), which is an Interventional X-ray imaging system.

Technological characteristics:

VesselNavigator employs comparable technology as its predicate device *MR-CT Roadmap*:

- Both tools run on a separate interventional tools workstation (Philips Interventional Workspot, K121296).
- Both tools provide basic viewing operations to manipulate image data.
- Both tools have comparable snapshot functionality.
- Both tools provide an overlay of live 2D fluoroscopy images on a 3D reconstruction (3D volume) of the vessel tree acquired from a previous MR or CT scan; in this way the 3D volume serves as a roadmap to provide additional information for navigating endovascular devices through vascular structures of the patient.
- Both tools support registration of 3D volume with the x-ray system.
- Both tools support manual correction of the registration.
- Both tools provide dynamic update to changes of the position of the X-ray equipment; the 3D volume is automatically adjusted to any gantry changes and any lateral or longitudinal table movements.
- Both tools have functionality to store roadmaps.
- Both tools can be controlled from the tableside.

The technological differences between **VesselNavigator** and its predicate device *MR-CT Roadmap* are noted below

- **VesselNavigator** provides functionality to measure distances. This function is identical to the reference device *HeartNavigator Release 2*.
- **VesselNavigator** provides functionality to segment the relevant vasculature in the 3D volume (where the end-user is able to edit the segmentation results), place landmarks for easy recognition of key anatomical points of interests, and store and recall of preferred view angles.
- **VesselNavigator** tools to remove the table and segment and remove specific bone structures from the view

As these differences are considered low risk (only providing further support to the clinicians in performing interventions) and the functionalities were verified and validated with equivalent methods, these differences do not raise new questions on safety or effectiveness.

Therefore, the **VesselNavigator** is substantially equivalent to the currently marketed predicate device *MR-CT Roadmap* in terms of technological characteristics.

Summary of Non-clinical Performance Data:

Non-clinical performance testing has been performed on **VesselNavigator** 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, 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).

Software verification testing has been performed to cover the main system level requirements as well as the identified hazard mitigations. Software validation testing included testing of the vessel segmentation tool, the intended use and commercial claims, and usability testing with representative intended users. All of these tests were used to support substantial equivalence of the subject device.

The test results in this 510(k) premarket notification demonstrate that **VesselNavigator**:

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

Therefore, **VesselNavigator** is substantially equivalent to the currently marketed predicate device *MR-CT Roadmap* in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The subject of this premarket submission, **VesselNavigator,** did not require clinical studies to support substantial equivalence.

Substantial Equivalence Conclusion:

The **VesselNavigator** software medical device is substantially equivalent to the currently marketed predicate device *MR-CT Roadmap* in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. The (non-)clinical performance tests provided in this 510(k) premarket notification demonstrates that the proposed **VesselNavigator** is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.