JUN 10 2014

K140138
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510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness has been prepared in accordance with Code of Federal Regulations, Title 21 CFR, Part 807.92.

Date Prepared:	May 23, 2014	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684 PC Best The Netherlands	
Contact Person:	Hans Venings Telephone: +31 61 1348827	
Device Name:	**HeartNavigator Release 2.0**	
Classification:	Classification regulation:	21 CFR, Part 892.1650
	Classification name:	Image-intensified fluoroscopic x-ray system
	Classification panel:	Radiology
	Device classification:	Class II
	Primary Product Code:	OWB
	Secondary Product Code:	LLZ
Primary[1] Predicate Device:	Trade name:	AlluraClarity Xper FD series X-ray system
	Manufacturer:	Philips Medical Systems Nederland B.V.
	FDA clearance:	K130638 (June 28, 2013)
	Classification regulation:	21 CFR, Parts 892.1650
	Classification name:	Image-intensified fluoroscopic x-ray system
	Classification panel:	Radiology
	Device classification:	Class II
	Product Code:	OWB
Secondary Predicate Device:	Trade name:	HeartNavigator Release 1.0
	Manufacturer:	Philips Medical Systems Nederland B.V.
	FDA clearance:	K111245 (July 29, 2011)
	Classification regulation:	21 CFR, Parts 892.2050
	Classification name:	Picture archiving and communications system
	Classification panel:	Radiology
	Device classification:	Class II
	Product Code:	LLZ

[1] The HeartNavigator software medical device is an accessory to the AlluraClarity Xper FD series X-ray system. The AlluraClarity Xper FD Series X-ray system will be abbreviated as Allura X-ray system in this 510(k) Summary of Safety and Effectiveness.

Indications for Use: HeartNavigator is a tool to assist the user with the treatment of structural heart diseases using minimal invasive interventional techniques. In addition to the conventional live fluoroscopy it provides the user with tools to plan and guide the procedure using 3D image data.

Device Description: The HeartNavigator software tool is intended to be used in combination with the primary predicate device Allura X-ray system (K130638) to assist cardiac surgeons and interventional radiologists with the planning and treatment of structural heart diseases using minimal invasive interventional techniques. In addition to conventional live fluoroscopy HeartNavigator provides the user with tools to plan and guide the procedure using 3D image data; by enabling the use of previously acquired DICOM cardiac CT data of the patient in conjunction with the X-ray image data from the Allura X-ray system. While HeartNavigator Release 1.0 (K111245) and Release 2.0 share the same technological characteristics, HeartNavigator Release 2.0 offers enhancements to existing functions, i.e., (1) automatic anatomical distance measurements, and (2) tracking movements of the table and L-arm of the connected Allura X-ray system during live guidance. The modifications represented by HeartNavigator Release 2.0 do not affect the safety and effectiveness of the device.

Performance Data: The HeartNavigator conforms to the following international standards:

- IEC 62366 Application of usability engineering to medical devices (2007);
- IEC 62304 Medical device software – Software life cycle processes (2006);
- ISO 14971 Application of risk management to medical devices (2007);
- NEMA PS 3.1–3.2 Digital Imaging and Communications in Medicine (DICOM) Set (2011).

Non-clinical verification and validation tests were performed with respect to the requirement specifications, including software verification and validation. The test results demonstrate that HeartNavigator Release 2.0 meets the acceptance criteria, and is adequate for its intended use.

Substantial Equivalence Conclusion: Substantial equivalence was demonstrated with non-clinical performance (verification and validation) testing, which complied with the requirements specified in the international, FDA-recognized consensus standards. The results of these tests demonstrate that the HeartNavigator Release 2.0 software medical device is safe, effective and performs as well or better than the secondary predicate device HeartNavigator Release 1.0 (K111245).

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

June 10, 2014

Philips Medical Systems Nederland B.V.
% Michael Dayton, MA, RAC
Senior Consultant
Biomed Research, Inc.
3959 Van Dyke Road, Suite 245
LUTZ FL 33558

Re: K140138
Trade/Device Name: HeartNavigator Release 2.0
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, LLZ
Dated: March 8, 2014
Received: March 13, 2014

Dear Mr. Dayton:

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.

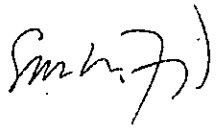
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140138

Device Name
HeartNavigator Release 2.0

Indications for Use *(Describe)*

HeartNavigator is a tool to assist the user with the treatment of structural heart diseases using minimal invasive interventional techniques. In addition to the conventional live fluoroscopy it provides the user with tools to plan and guide the procedure using 3D image data.

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.

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