510(k) Summary

JUL 10 2014

This 510(k) summary is prepared in accordance with 21 CFR 807.92.

Date Prepared: December 5, 2013

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

Contact Person:
Ruojuan Zhang
Regulatory Affairs Manager
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Device Name: Veradius

Classification:	Classification Name:	Interventional Fluoroscopic X-Ray System
	Classification Regulation:	21 CFR892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary product code:	OWB
	Secondary product code	OXO
Predicate Device	Trade Name:	Veradius
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K090590 (March 16, 2009)
	Classification Regulation:	21 CFR, Part 892.1650
	Classification Name:	Interventional Fluoroscopic X-Ray System
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	OWB; JAA

Device description: The proposed **Veradius R1.2** is a counterbalanced C-arm with a thin flat detector x-ray system. The system consists of two main component parts: the C-arm stand (comprising X-ray generator and X-ray tube, Flat Detector and the X-ray control user interface) and the mobile viewing station (comprising the image processor, monitors, user interface for image/patient handling and optionally an integrated workstation).

Indications for Use:

The proposed **Veradius R1.2** device is intended to be used and operated by: adequately trained, qualified, and authorized health care professionals such as physicians, surgeons, cardiologists, radiologists, and radiographers, who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device.
The device is used for radiological guidance and visualization during diagnostic, interventional, and surgical procedures on all patients except neonates (birth to 1 month), within the limits of the device. The device is to be used in healthcare facilities both inside and outside the operating room, in sterile as well as non-sterile environments, in a variety of procedures.

Applications

- Orthopedic
- Neuro
- Abdominal
- Vascular
- Thoracic
- Cardiac

The proposed Philips **Veradius R1.2** has identical indications to the currently marketed and predicate Veradius Mobile C-arm X-ray system (Veradius R1.1).

Technology:

The technology used in the development of the major components of the proposed **Veradius R1.2** which includes X-ray generator, X-ray tube housing assembly, Image detection system and beam limiting device is identical to the currently marketed and predicate Veradius R1.1. The changes being proposed in this submission for the proposed **Veradius R1.2**, when compared to the currently marketed and predicate Veradius R1.1, are as follows:

- New C-arc geometry
- Wireless LAN connection (without support of DHCP)
- New Flat Detector(model: Pixium 2630Sv)
- Additional display of dose information on Mobile Viewing Station
- DICOM Structured Dose Reporting

Based on the information provided in this premarket notification, the **Veradius R1.2** is considered substantially equivalent to the currently marketed and predicate devices in terms of:

- Indications for use;
- Basic Design Features;
- Fundamental scientific technology;
- Operating Principle and control mechanism.

Non-clinical Performance Data:

Non-clinical performance testing has been performed on the proposed **Veradius R1.2** and demonstrates compliance with International and FDA-recognized consensus standards and FDA guidance document.

- IEC 60601-2-43 (2010)
- IEC 60601-2-28 (2010)
- ISO 14971 (2007
- ISO 62304 (2006)
- FDA Guidance document entitled, *"Guidance for the Premarket*

Submissions for Software Contained in Medical Devices" issued May 11, 2005.

- FDA Guidance document entitled, *"Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices"* issued August 6, 1999
- FDA Guidance *"Radio Frequency Wireless Technology in Medical Devices"* issued August 14, 2013

Additionally, verification and validation tests have been performed to address intended use, the technical claims, requirement specifications, image quality and the risk management results.
The test results demonstrate that the proposed **Veradius R1.2**

- Complies with the aforementioned international and FDA-recognized consensus
- Meets the acceptance criteria and is adequate for its intended use.
- Image Quality is equal to the predicate.

Therefore, the proposed **Veradius R1.2** is substantially equivalent to the currently marketed and predicate device (K090590, March 16, 2009) in terms of safety and effectiveness.

Clinical Performance Data: The subject of this premarket submission, the **Veradius R1.2** did not require clinical studies to support substantial equivalence.

Conclusion: The proposed **Veradius R1.2** are substantially equivalent to the currently marketed and predicate Veradius Mobile X-Ray system with regards to :

- Indications for use;
- Basic Design Features;
- Fundamental scientific technology;
- Operating Principle and control mechanism.

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

July 10, 2014

Philips Medical Systems Nederland BV
% Dr. Ruojuan Zhang
Regulatory Affairs Manager
Veenpluis 4-6
Best 5684 PC
THE NETHERLAND

Re: K133819
Trade/Device Name: Veradius
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA, OWB
Dated: April 3, 2014
Received: April 7, 2014

Dear Dr. Zhang:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133819

Device Name
Veradius

Indications for Use *(Describe)*
The Veradius device is intended to be used and operated by: adequately trained, qualified, and authorized health care professionals such as physicians, surgeons, cardiologists, radiologists, and radiographers, who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device.
The device is used for radiological guidance and visualization during diagnostic, interventional, and surgical procedures on all patients except neonates (birth to 1 month), within the limits of the device. The device is to be used in health care facilities both inside and outside the operating room, in sterile as well as nonsterile environments, in a variety of procedures.

Applications
- Orthopedic
- Neuro
- Abdominal
- Vascular
- Thoracic
- Cardiac

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)*