K090590

510(k) Summary of Veradius device

MAR 16 2009

In accordance with the requirements of 21 CFR 807.92

1) Submitted by

Philips Medical Systems North America Company
22100 Bothell Everett Highway
Bothell, WA 98021
Establishment Registration No. 1217116

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Date prepared:	*November 10, 2008*

2) Manufacturer

Philips Medical Systems Nederland B.V.
Veenpluis 4-6
5684 PC Best
The Netherlands
Establishment Registration No. 3003768277

3) Device name and classification

Trade name:	*VERADIUS*
Classification name:	*System, x-ray, mobile and Solid State X-Ray Imager (Flat Panel/Digital Imager)*
Classification panel:	*Radiology devices*
Regulatory status:	*Class II*
Device classification reg.nr:	*21CFR 892.1720 Class II (IZL) and 21 CFR 892.1650 Class II (MQB)*

4) Predicate device

Device name:	*Pulsera*
K-Number:	*K061685*
Trade name:	*3D-RX Option for BV Pulsera, Release 2.2*
Manufacturer:	*Philips Medical Systems Nederland B.V.*

5) Device description (summarized)

The Veradius device is a Mobile C-arm X-ray System designed for medical applications during diagnostic, interventional and surgical procedures.
The device consists mainly of two 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, mains control unit, an user interface for image/patient handling and optionally an integrated workstation).
All movements of the C-arm stand are manual except the height movement. The Mobile viewing station can be used standalone for reviewing and archiving purposes.

6) Indications for Use

The Veradius device is intended to be used and operated by: adequately trained, qualified and authorized health care professionals such as physicians, surgeons, cardiologist, 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 babies, within the limits of the device. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.

Applications:

Orthopedic
Neuro
Abdominal
Vascular
Thoracic
Cardiac

7) Technological characteristics and substantial equivalence

The Veradius does not introduce any new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems Nederland BV considers the Veradius to be substantially equivalent with the predicate device.

The Veradius is a mobile X-ray system consisting of components mention in Table 1 Device Comparison.

All units are the same as in the predicate device and known to FDA, except 4 and 5.

Image Detection Subsystem

The Image Detection Subsystem (IDS) is new. For the Veradius the IDS based on an Image Intensifier is replaced by an IDS with a Flat Detector. The IDS detect X-rays and convert them to digital images, and apply calibration to obtain the required data.

The function (intended use) of the Image Detection Subsystem is not different from its predicate device. Only the technologic characteristics are different.
The new IDS consist out of an anti scatter grid, a flat dynamic X-ray detector and a detector controller.
The new technologic characteristic does not affect safety or introduce any new type of hazards.

Table 1 Device Comparison

		Pulsera		Veradius	
		Manufacturer	Model	Manufacturer	Type
1	X-ray generator	Gilardoni	iXion HF Generator	Gilardoni	iXion HF Generator
2	X-ray tube housing assembly	Gilardoni	iXion Monoblock with X-ray tube from Philips RO-0306	Gilardoni	iXion Monoblock with X-ray tube from Philips RO-0306
3	Beam Limiting Device	PMS Ned. BV	X-ray beam collimator BV300	PMS Ned. BV	X-ray beam collimator BV300
4	Image Detection Subsystem	PMS Ned. BV	IDS-7 Circular grid. Detector is a 9" or 12" II with digital camera. Controller integrated in camera.	PMS Ned. BV	FDS S FL1.1 Rectangular grid. Flat detector. Separate FD controller.
5	Detector laser aiming device	LAB Laser	Mounted with belt around II	PMS Ned. BV	Integrated in FD covers.
6	Laser Alignment Tool	PMS Ned. BV	Laser Alignment Tool BV300	PMS Ned. BV	Laser Alignment Tool BV300
7	Mobile C-arm Stand	PMS Ned. BV	C-arm Stand BV Family R2	PMS Ned. BV	C-arm Stand BV Family R2
8	Mobile Viewing Station	PMS Ned. BV	MVS BV Family R2	PMS Ned. BV	MVS BV Family R2
9	Indications for Use	PMS Ned. BV	Refer to 510(k) K061685	PMS Ned. BV	Indications for Use are equal to Pulsera. Refer to chapter 6.

8) Non-Clinical and Clinical performance tests

Non-Clinical and clinical tests have been performed to verify and validate the system functionality for the intended use. Results of the conducted tests conclude that the Veradius is substantial equivalent to its predicate device.
Based on comparison between images pairs taken during non-clinical and clinical performance tests with the Veradius and its predicate device, it can be concluded that the Image Quality is equal or even better.

9) Safety information

The Level of Software concern is MODERATE as determined according to the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May/11/2005.

A product risk management is executed and all risks are reduced to an acceptable level by implementation and verification of appropriate measures.

Philips Medical Systems North America Company feels that sufficient information and data are contained in this submission to enable CDRH to reach a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL 30 2012

Philips Medical Systems, North America Company
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K090590
Trade/Device Name: Veradius
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: March 3, 2009
Received: March 4, 2009

Dear Mr. Job:

This letter corrects our substantially equivalent letter of March 16, 2009.

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

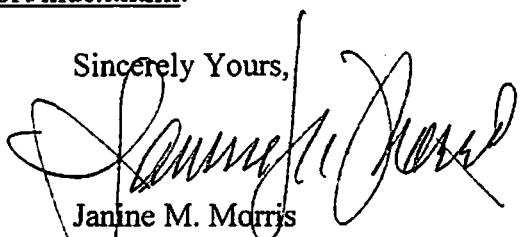
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090590

Device Name: **Veradius**

Indications For Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K090590