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

October 22, 2014

Philips Medical Systems Netherlands BV
% Ms. Jeanette Becker
Regulatory Affairs Manager
Veenpluis 4-6
BEST 5684 PC
THE NETHERLANDS

Re: K142708
Trade/Device Name: Veradius Unity
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, OXO, JAA
Dated: September 16, 2014
Received: September 22, 2014

Dear Ms. Becker:

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)*

K142708

Device Name
Veradius Unity

Indications for Use *(Describe)*

The Veradius Unity 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 one 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 non-sterile 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)*

510(k) Summary

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

Date Prepared:	September 16, 2014	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684 PC Best The Netherlands Establishment Registration Number: 3003768277	
Contact Person:	Jeanette Becker Regulatory Affairs Manager Phone: +31611386380 Fax: +31 40 2769100 E-mail: jeanette.becker@philips.com	
Device Name:	Veradius Unity	
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; JAA
Predicate Device	Trade Name:	Veradius
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K133819 (July 10, 2014)
	Classification Regulation:	21 CFR, Part 892.1650
	Classification Name:	Interventional Fluoroscopic X-Ray System
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	OWB; OXO; JAA

Device description: The proposed **Veradius Unity** 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 Unity** 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 one 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 Unity** has identical indications to the currently marketed and predicate Veradius Mobile C-arm X-ray system (Veradius R1.2).

Technology: The technology used in the development of the major components of the proposed **Veradius Unity** 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 R1.2. The significant changes being proposed in this submission for the proposed **Veradius Unity**, when compared to the currently marketed and predicate Veradius R1.2, are as follows:

- New C-arm stand user interface:
  The stand user interface in the predicate Veradius system is based on hard buttons and a small monochrome display. This user interface has been replaced in the proposed **Veradius Unity** by a touch screen based user interface. The touch screen enables the end user to change and make any settings or pre-sets, but also displays the X-ray image which has just been taken by the physician.
- Position tracking(optional):
  The predicate Veradius system as well as the proposed **Veradius Unity** system has printed scales on the C-arc as reference for the geometrical position of the C-arc. The proposed **Veradius Unity** system can optionally be equipped with sensors on four C-arc axes to digitally read-out the geometrical position of these axes. The user can also store up to three positions for reference (Position Memory) which will indicate how to get back to these positions.
- Outline tool (Optional):
  On the proposed **Veradius Unity** system a digital equivalent of a marker pen has been implemented to draw vessel outlines and other anatomical references on the imaging monitor.
- ClearGuide:
  The ClearGuide function provided on the proposed **Veradius Unity** system is to improve the communication in the Operation Room

between Surgeon and Operator by correlating directions (up/down/left/right) in the image with physical markers (3/6/9/12) on the detector.

- Wireless footswitch (Optional):
  The predicate Veradius System is equipped with a footswitch that is connected by wire to the system. The proposed **Veradius Unity** system offers the possibility to optionally use a wireless footswitch in addition to the wired footswitch
- Electronic Blanking:
  For the predicate Veradius System at higher voltage, the shutters on the x-ray image may look gray instead of black. On the proposed **Veradius Unity** system these lead shutters are overlaid by a black area (blanking) on the shown x-ray image. This blanked (black) area will not be shown as long as the physical shutters are still moving. Only when the physical shutter has reached its requested end-position after movement, the blanking will appear.

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

- Indications for use;
- Fundamental scientific technology;
- Design and functionality;
- Performance specifications and testing.

Non-clinical Performance Data:

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

- IEC 60601-2-43 (2010)
- IEC 60601-2-28 (2010)
- IEC 62366(2007)
- 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 *"Radio Frequency Wireless Technology in Medical Devices"* issued August 14, 2013

Additionally, the following verification and validation tests have been performed to address intended use, the technical claims, requirement specifications, usability and the risk management results for the significant changes:

- New C-arm stand user interface:
  - Prepare for acquisition
  - Stand User Interface functions including the new concept SW controls
  - Image reviewing and supporting functions
  - Stand User Interface panel controls

    - GUI behavior and state transitions
- Position tracking(optional)
    - Accuracy
    - Serviceability
    - Calibration
- Outline tool (Optional)
    - Free format drawing on live fluoro images
    - Full editing functions including delete, undo, disable, enable
- ClearGuide
    - The function is activated from the Stand User Interface
    - Indicators are displayed on the examination monitor, stored to USB, printed with the internal printer.
    - Actual indicators are placed on the detector
- Wireless footswitch (Optional)
    - Startup/shutdown
    - Functional test on X-Ray modes
    - Coexistence with other wireless devices
- Electronic Blanking
    - Image Quality

The results from the verification and validation tests as mentioned above demonstrate that the proposed **Veradius Unity**:
• Meets the acceptance criteria and is adequate for its intended use;
• Complies with the aforementioned international and FDA-recognized consensus.

Therefore, the proposed **Veradius Unity** is substantially equivalent to the currently marketed and predicate device (K133819, July 10, 2014) in terms of safety and effectiveness.

Clinical Performance Data:

The subject of this premarket submission Veradius Unity did not require clinical studies to support substantial equivalence because the Veradius Unity utilizes identical components throughout the imaging chain and the system's equivalent performance in light of the modifications could be supported through verification and validation testing alone."

Conclusion:

The modifications of the device are verified and validated to ensure that the modifications are properly introduced; conformance to IEC standards and guidance documents. All of these tests were used to support substantial equivalence of the subject device. The proposed **Veradius Unity** is substantially equivalent to the currently marketed and predicate Veradius R1.2 system with regards to :

- Indications for use;
- Fundamental scientific technology;
- Design and functionality;
- Performance specifications and testing.