DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 25, 2016

Philips Medical Systems Nederland BV
Image Guided Therapy (IGT) Systems
Jeanette Becker
Regulatory Affairs Manager
Veenpluis 4-6
Best, 5684PC
NETHERLANDS

Re: K160455
Trade/Device Name: AneurysmFlow
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, LLZ
Dated: July 22, 2016
Received: July 25, 2016

Dear Jeanette 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 Robert Ochs, Ph.D.
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)*
K160455

Device Name
AneurysmFlow

Indications for Use *(Describe)*
AneurysmFlow assists during endovascular procedures for treating of saccular cerebral aneurysms, by:
• Visualization of blood flow patterns in the aneurysm and parent vessel, based on digital subtraction angiography.
• Quantification of the blood flow in the aneurysm parent vessel, based on digital subtraction angiography and 3D rotational angiography.
• Comparison of blood flow, both visual and quantified between two acquisitions.

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.

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510(k) Summary

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

Date Prepared:	February 15, 2016	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 4-6 5684 PC Best The Netherlands Establishment Registration Number: 3003768277	
Primary Contact Person:	Ms. Jeanette Becker Regulatory Affairs Manager Phone: +31 611386380 E-mail: jeanette.becker@philips.com	
Secondary Contact Person:	Ms. Liselotte Kornmann, PhD Senior Manager Regulatory Affairs Phone: +31 611621238 E-mail: liselotte.kornmann@philips.com	
Device:	Trade Name:	AneurysmFlow
	Device Name:	AneurysmFlow
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product code: Secondary Product Code:	OWB (Interventional x-ray system) LLZ (system, image processing, radiological)
Primary Predicate Device:	Trade Name:	2D Perfusion
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K132147 (Dec 16, 2013)
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21 CFR, Part 892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Primary Product code: Secondary Product Code:	OWB LLZ
Reference Device 1:	Trade Name:	3D Roadmap
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K121772 (March 21, 2013)

Reference Device 2:	Trade Name:	EP Navigator
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K142126 (December 9, 2014)

Device description:

AneurysmFlow is a software tool intended to provide relevant information on the blood flow in a cerebral aneurysm and its parent artery based on angiography. **AneurysmFlow** is a software medical device and is intended to be used in combination with the currently marketed Philips interventional X-ray system and 3D volume data from 3D Rotational Angiography. **AneurysmFlow** is a software product (Interventional Tool) that provides color coded and vector field representation of a digital subtraction angiography (DSA). It can quantify blood flow rates in the artery based on DSA and 3D-RA data. It can visualize blood flow patterns in an aneurysm based on DSA data. It can also provide a side by side visual and quantitative comparison between two acquisitions.

Indications for Use:

AneurysmFlow *assists during endovascular procedures for treating of saccular cerebral aneurysms, by:*

- *Visualization of blood flow patterns in the aneurysm and parent vessel, based on digital subtraction angiography.*
- *Quantification of the blood flow in the aneurysm parent vessel, based on digital subtraction angiography and 3D rotational angiography.*
- *Comparison of blood flow, both visual and quantified between two acquisitions.*

The indications for use of **AneurysmFlow** are similar to the primary currently marketed and predicate device 2D Perfusion except that:

- The use of **AneurysmFlow** is limited to cerebral vessels instead of all vessels
- **AneurysmFlow** also provides quantification of flow in addition to a color coded visualization

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 devices have the same intended use: they are accessories to the currently marketed Philips interventional X-ray system and provide additional information derived from the time intensity curve of a digital subtraction angiography (DSA) run to support the user during interventional procedures.

Technological characteristics:

AneurysmFlow employs comparable technological characteristics as the predicate device 2D Perfusion:

- Both devices are accessories to the currently marketed Philips interventional X-ray system and use angiography X-ray images from this system as input.
- Both devices run on the (separate) currently marketed Interventional Tools Workstation (Philips Interventional Workspot).

- Both devices use a dedicated real-time link with the Interventional X-ray system to acquire live 2D fluoroscopy images and exam data.
- Both devices provide a mechanism to the user to mark a region of interest in which the flow parameters are derived.
- Both devices provide color coded representation of parameters derived from a digital subtraction angiography (DSA).
- Both devices provide side by side comparison of information from two acquisitions.
- Both devices provide visualization of contrast density over time in a time-graph and color image format.
- Both devices provide basic viewing operations to manipulate image data that is shown in the viewers.
- Both devices provide a mechanism to the user to synchronize interactions (like changing the region of interest) across compared runs.
- Both devices provide a mechanism to the user to take a snapshot of the main display area.
- Both devices provide a mechanism to the user to export displayed information.

AneurysmFlow is different from the currently marketed and predicate device 2D Perfusion with regards to the following technological characteristics:

- The **AneurysmFlow** algorithm derives flow information from digital subtraction angiography (DSA) data using the modulation in contrast concentration resulting from the heart rhythm, whereas the currently marketed and predicate device 2D Perfusion uses time to peak and wash in rate parameters. This difference does not raise new questions on safety and effectiveness and existing verification methods showed both algorithms provide accurate results.
- **AneurysmFlow** provides a mechanism to the user to quantify the arterial flow in the user chosen arterial segment of the main feeding artery of the aneurysm, whereas the currently marketed and predicate device 2D perfusion visualizes the mean transit time. For calculation of volumetric flow in the artery, **AneurysmFlow** uses 3D volume data in conjunction with the DSA data. This does not raise new questions on safety and effectiveness since the flow calculation from DSA and 3D volume data only provides additional information to the user and the user can observe if the registration of DSA data with 3D volume data and segmentation within the 3D volume data is correct and reject / reselect a 3D volume. Furthermore, the technology to register 3D volume data with 2D images is identical to the technology used in reference device 3D Roadmap (K121772).
- **AneurysmFlow** provides the flow information not only in color image format but also as a vector field, time graph and in a

numerical representation. As these are only different representations of the derived parameters from the digital subtraction angiography (DSA), this difference does not raise new questions on safety and effectiveness.

- **AneurysmFlow** provides automatic position control (APC) to recall C-arm orientations from previous acquisitions, whereas with the currently marketed and predicate device 2D Perfusion, users have to manually position the C-arm orientations from previous acquisitions. As the APC feature is only adding convenience, this difference does not raise new questions on safety and effectiveness. Furthermore, this technology is identical to the reference device EP Navigator (K142126).

Based on the information provided above, **AneurysmFlow** is considered substantially equivalent to the primary currently marketed and predicate device 2D Perfusion and references devices 3D Roadmap and EP Navigator in terms of technological characteristics.

Summary of Non-Clinical Performance Data:

The **AneurysmFlow** complies with the following international and FDA-recognized consensus standards:

- IEC 62304 Medical device software – Software life cycle processes (Ed. 1.0, 2006),
- IEC 62366-1 Medical devices – Application of usability engineering to medical devices (Ed. 1.0, 2015),
- 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),
- 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)

The following non-clinical performance data were provided in support of the substantial equivalence determination.

Software verification testing (functionality, interoperability, privacy and security, performance, reliability, safety, and Allura compatibility) has been performed to cover system level requirements and the risk control measures. Results demonstrated that all executed tests were passed.

Algorithm verification testing has been performed to support the accuracy of the algorithm used. Results demonstrated that the algorithm confirms to its specifications.

Non-clinical software validation testing has been performed to cover the intended use, commercial claims, service user needs, effectiveness of safety measures, instructions for use, and usability testing with representative intended users. Results demonstrated that the **AneurysmFlow** conforms to its intended use and user needs and has proven to be safe and effective.

Therefore, **AneurysmFlow** is substantially equivalent to the primary currently marketed and predicate device 2D Perfusion in terms of safety and effectiveness.

Summary of Clinical Performance Data:

AneurysmFlow did not require clinical studies since substantial equivalence to the primary currently marketed and predicate device 2D Perfusion was demonstrated with the following attributes:

- Indication for use;
- Technological characteristics;
- Non-clinical performance testing; and
- Safety and effectiveness.

Sample clinical images of one case accompanied by signed statements from three board certified neuroradiologists were provided to demonstrate that after completing all worksteps, the presented data are consistent with the raw data (X-ray angiogram).

Substantial Equivalence Conclusion:

AneurysmFlow is substantially equivalent to the primary currently marketed and predicate device 2D Perfusion (K132147) in terms of indications for use, technological characteristics and safety and effectiveness.

Additionally, substantial equivalence was demonstrated with non-clinical performance (verification and validation) tests, which complied with the requirements specified in the international and FDA-recognized consensus standards, IEC 62304, IEC 62366-1 and ISO 14971. The results of these tests demonstrate that **AneurysmFlow** met the acceptance criteria and is adequate for this intended use.