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DEC 16 2013

510(k) Summary of Safety and Effectiveness

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

Date Prepared: July 8, 2013

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

Contact Person:
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Device Name: **2D Perfusion**

Classification:

Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Regulation:	21CFR §892.1650
Classification Panel:	Radiology
Device Class:	Class II
Primary Product Code:	OWB (Interventional x-ray system)
Secondary Product Code:	LLZ (system, image processing, radiological)

Primary Predicate Device 1:

Trade Name:	Allura Xper FD20 X-Ray Imaging Systems
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K033737 (December 9, 2003)
Classification Regulation:	21 CFR, Part 892.1650
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	OWB (interventional fluoroscopic x-ray system)

Primary Predicate Device 2:

Trade Name:	Allura Xper FD OR Table Series
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K102005 (August 9, 2010)
Classification Regulation:	21 CFR, Part 892.1650
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	OWB (interventional fluoroscopic x-ray system)

Secondary Predicate Device:

Trade Name:	AW VolumeShare 5 with AngioViz Option
Manufacturer:	GE Healthcare
510(k) Clearance:	K110834 (April 26, 2011)
Classification Regulation:	21CFR §892.1600
Classification Name:	Picture archiving and communications system
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	LLZ (system, image processing, radiological)

Note: The **2D Perfusion** software medical device is considered an accessory to the following currently marketed and predicate devices and thus designated with the primary product code of OWB:

- Philips Allura Xper FD20 X-Ray Imaging Systems (K033737); and
- Philips Allura Xper FD OR Table Series (K102005).

Since the **2D Perfusion** is a software medical device and is an accessory to the currently marketed Philips Allura Xper X-ray Systems, substantial equivalence demonstration is not warranted.

Device description: The **2D Perfusion** software medical device is a tool that assists the physician in the diagnosis of perfusion (i.e., passage of blood through blood vessels to an organ or a tissue) alterations by providing a color coded representation of a digital subtraction angiography (DSA) run. The **2D Perfusion** software medical device can visualize multiple functional parameters related to the time-density function and also provides a comparison between pre-, peri-, and post-procedural color coded images.

Indications for Use: **2D Perfusion** assists in the diagnosis of perfusion alterations of tissues, based on digital subtraction angiography (DSA), by providing color coded images generated from the DSA series.

Note: The indication for use of the **2D Perfusion** software medical device and the currently marketed and secondary predicate AngioViz Option provided with the AW VolumeShare 5 workstation (GE Healthcare, K110834) are similar as follows:

- Produces / provides parametric images from a DSA series to enable the user to more easily visualize vascular flow.

The differences between the **2D Perfusion** software medical device and the currently marketed and secondary predicate AngioViz Option provided with the AW VolumeShare 5 workstation (GE Healthcare, K110834) are:

- The currently marketed and secondary predicate AngioViz Option produces from a DSA series parametric images representing maximum (peak) opacification, time to peak, and combinations of those, to enable the user to more easily visualize characteristics related to vascular flow.
- The **2D Perfusion** software medical device provides the following parameters to enable the user to more easily visualize characteristics related to vascular flow: arrival time, time to peak, wash-in rate, width, area under the curve, and means transit time.

The parameters provided with the **2D Perfusion** does not affect the safety or effectiveness since they provide a different representation of information already present in the input DSA images to enable the user to more easily visualize characteristics related to vascular flow as compared to the parameters provided by the currently marketed and secondary predicate AngioViz Option provided with the AW VolumeShare 5 (GE Healthcare, K110834). Thus, the differences in the indications for use do not impact the safety and effectiveness of this product.

Based on the information provided above, **2D Perfusion** is considered substantially equivalent to the currently marketed and secondary predicate AngioViz Option provided with the AW VolumeShare 5 workstation (GE Healthcare, K110834) in terms of indication for use.

Technology:

The fundamental scientific technology of both the currently marketed and secondary predicate AngioViz Option provided with the AW VolumeShare 5 workstation (GE Healthcare, K110834) and **2D Perfusion** software medical device, is as follows:

- *Execution on and connection to an independent software hosting platform / workstation, which supports functions for image display, manipulation, and selective recording, import, export and data handling.*

  The **2D Perfusion** software medical device is provided on the independent hosting software platform, Philips Interventional Workspot (K121296, January 2, 2013). The currently marketed Philips Interventional Workspot software platform, which support 510(k) cleared Philips Interventional Tools, provides common functionalities (e.g., import / export and data handling functions) that are required by the Interventional Tools to support the physician with performing the Interventional procedure.

- *Provide visualization of parameters derived from the time intensity curve of a DSA input run.*

  Based on analysis of the time intensity curve of the input DSA, the currently marketed and secondary predicate AngioViz Option provided with the AW VolumeShare 5 workstation (GE Healthcare, K110834) provides images of the following derived parameters:
  - *Peak opacification*: the maximum intensity of the time intensity curve;
  - *Time to peak*, the time between the first arrival of contrast medium and the moment it reaches its maximum concentration; and
  - *Peak opacification to time to peak ratio.*

  Based on analysis of the time intensity curve of the input DSA, **2D Perfusion** provides images of the following derived parameters:
  - *Time to peak*: the time between the first arrival of contrast medium and the moment it reaches its maximum concentration. This yields the same information as the time to peak provided by the predicate

AngioViz Option; and

- *Wash-in rate*: the slope of the time intensity curve between arrival time and time to peak. This yields similar information as the peak opacification to time to peak ratio provided by the predicate AngioViz Option.

In addition, **2D Perfusion** provides images of the following derived parameters which are not provided by the predicate AngioViz Option:

- *Arrival time*: the time between the start of the DSA run and the moment of arrival of contrast medium;
- *Width*: the time during which the time intensity curve is at least at half its maximum intensity;
- *Area under the curve*: the total accumulated intensity between the first of arrival of contrast medium and the moment of leveling off after the contrast bolus has passed; and
- *Mean transit time*: the time between the first of arrival of contrast medium and the moment of leveling off after the contrast bolus has passed.

The additional parameters visualized by **2D Perfusion** as well as the absence of the *Peak opacification* visualization do not affect the safety or effectiveness since both the predicate AngioViz Option and **2D Perfusion** provide visualization of parameters derived from the time intensity curve. Thus, the differences in the technology do not impact the safety and effectiveness of this product.

Based on the information provided above, **2D Perfusion** is considered substantially equivalent to the currently marketed and secondary predicate AngioViz Option provided with the AW VolumeShare 5 workstation (GE Healthcare, K110834) in terms of technology.

Summary of Non-clinical Performance Data:

The **2D Perfusion** software medical device complies with the following international and FDA-recognized consensus standards:

- IEC 62304 *Medical device software – Software life cycle processes* (2006);
- IEC 62366 *Application of usability engineering to medical devices* (2007);
- ISO 14971 *Application of risk management to medical devices* (2007).

Non-clinical software verification and validation tests have been performed with regards to the intended use, the technical claims, the requirement specifications and the risk management results. The non-clinical software verification and validation test results demonstrate that the **2D Perfusion** software medical device complies with international and FDA-recognized consensus standards and meets the acceptance criteria and is adequate for its intended use. Therefore, the **2D Perfusion** software medical device is substantially equivalent to the currently marketed and secondary predicate AngioViz Option provided with the AW VolumeShare 5 workstation (GE Healthcare, K110834) in terms of safety and effectiveness.

Summary of Clinical Data:

The **2D Perfusion** software medical device did not require clinical studies since substantial equivalence to the currently marketed and predicate device was

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demonstrated with the following attributes:

- Design features;
- Indication for use;
- Fundamental scientific technology;
- Non-clinical performance testing; and
- Safety and effectiveness.

Substantial Equivalence Conclusion:

The **2D Perfusion** software medical device is substantially equivalent to the currently marketed and secondary predicate AngioViz Option provided with the AW VolumeShare 5 workstation (GE Healthcare, K110834) in terms of design features, fundamental scientific technology, indications for use, 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 and ISO 14971. The results of these tests demonstrate that the **2D Perfusion** software medical device met the acceptance criteria and is adequate for this intended use.

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

December 16, 2013

Philips Medical Systems Nederland B.V.
% Liselotte Kornmann, Ph.D.
Regulatory Affairs Manager
Veenpluis 4-6
5684 PC Best
THE NETHERLANDS

Re: K132147
Trade/Device Name: 2D Perfusion
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, LLZ
Dated: November 5, 2013
Received: November 7, 2013

Dear Dr. Kornmann:

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.

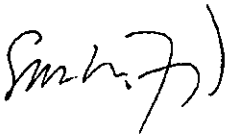
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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/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 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/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)*
K132147

Device Name
2D Perfusion

Indications for Use *(Describe)*
2D Perfusion assists in the diagnosis of perfusion alterations of tissues, based on digital subtraction angiography (DSA), by providing color coded images generated from the DSA series.

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)*

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