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

July 29, 2016

Philips Medical Systems Nederland BV
% Ms. Jeanette Becker
Regulatory Affairs Manager
Veenpluis 4-6
Best NL 5684PC
NETHERLANDS

Re: K161839
Trade/Device Name: 2D Quantitative Analysis
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, LLZ
Dated: June 30, 2016
Received: July 05, 2016

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

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)*

K161839

Device Name

2D Quantitative Analysis

Indications for Use *(Describe)*

2D Quantitative Analysis is a post processing software medical device intended to assist physicians through providing quantitative information as additional input for their comprehensive diagnosis decision making process and planning during cardiovascular procedures and for post procedural evaluation. 2D Quantitative Analysis consists of six applications:

The 2D Quantitative Coronary Analysis application is intended to be used for quantification of coronary artery dimensions (approximately 1 to 6 mm) from 2D angiographic images.

The 2D Quantitative Vascular Analysis application is intended to be used for quantification of aortic and peripheral artery dimensions (approximately 5 to 50 mm) from 2D angiographic images.

The 2D Left Ventricle Analysis and the Biplane 2D Left Ventricle Analysis applications are intended to be used for quantification of left ventricular volumes and local wall motion from monoplane and from biplane angiographic series, respectively.

The 2D Right Ventricle Analysis and the Biplane 2D Right Ventricle Analysis applications are intended to be used for quantification of right ventricular volumes and local wall motion from monoplane and from biplane angiographic series, respectively.

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:	June 30, 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:	**2D Quantitative Analysis**
	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 (Interventional Fluoroscopic X-Ray system) LLZ (System, Image Processing, Radiological)
Predicate Device:	Trade Name:	*Allura Xper FD series / Allura Xper OR Table series*
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K141979 (Aug 19, 2014)
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21 CFR, Part 892.1650
	Classification Panel:	Radiology
	Device Class:	Class II
	Product Code:	OWB, JAA

Device description: **2D Quantitative Analysis** is a software application that assists the user with quantification of

- vessels and vessel obstructions,
- ventricular volumes and
- ventricular wall motion

from angiographic X-ray images. The software provides semi-automatic contour detection of vessels, catheters and the left ventricle in angiographic X-ray images, where the end-user is able to edit the contours. **2D Quantitative Analysis** implements computational models for the quantification of vessels, obstructions in vessels, ventricular volumes and ventricular local wall motion from 2D contours.

The proposed **2D Quantitative Analysis** will be offered as an optional accessory to the Philips Interventional X-ray systems. Currently, the Quantitative Analysis functionality (Pie Medical Imaging, K100292) is embedded in the software of the currently marketed and predicate *Allura Xper FD series / Allura Xper OR table series* (K141979).

Indications for Use: The **2D Quantitative Analysis**, provided as optional accessory to the Philips Interventional X-ray system, has the following indications for use:

2D Quantitative Analysis *is a post processing software medical device intended to assist physicians through providing quantitative information as additional input for their comprehensive diagnosis decision making process and planning during cardiovascular procedures and for post procedural evaluation.* ***2D Quantitative Analysis*** *consists of six applications:*

The ***2D Quantitative Coronary Analysis*** *application is intended to be used for quantification of coronary artery dimensions (approximately 1 to 6 mm) from 2D angiographic images.*

The ***2D Quantitative Vascular Analysis*** *application is intended to be used for quantification of aortic and peripheral artery dimensions (approximately 5 to 50 mm) from 2D angiographic images.*

The ***2D Left Ventricle Analysis*** *and the* ***Biplane 2D Left Ventricle Analysis*** *applications are intended to be used for quantification of left ventricular volumes and local wall motion from monoplane and from biplane angiographic series, respectively.*

The ***2D Right Ventricle Analysis*** *and the* ***Biplane 2D Right Ventricle Analysis*** *applications are intended to be used for quantification of right ventricular volumes and local wall motion from monoplane and from biplane angiographic series, respectively.*

The indications for use statement of the **2D Quantitative Analysis** is not similar compared to the currently marketed *Allura Xper FD series / Allura Xper OR Table series* containing the embedded Quantitative Analysis functionality since the indications of the predicate's Quantitative Analysis functionality was not described specifically in the indications for use of the *Allura Xper FD series / Allura Xper OR Table series*. However, the difference in wording of the indications for use does not raise any new safety and effectiveness questions since the indications for use of the new device falls within the intended use of the predicate device and, therefore, the two devices have the same intended use. Both the predicate and subject device offer similar Quantitative Analysis functionality

and are intended to support the physician by providing vessel and ventricle dimensions from angiographic X-ray images.

Based on the information provided above**, 2D Quantitative Analysis** is substantially equivalent to the currently marketed *Allura Xper FD series / Allura Xper OR Table series* in terms of Indications for Use.

Technological characteristics:

2D Quantitative Analysis employs comparable technology as the Quantitative Analysis functionality embedded in the currently marketed *Allura Xper FD series and Allura Xper OR Table series*:

- Both tools provide the same Quantitative Analysis programs: Quantitative Coronary Analysis (QCA), Quantitative Vascular Analysis (QVA), Left Ventricle Analysis (LVA), Right Ventricle Analysis (RVA), LVA biplane and RVA biplane.
- Both tools support the same methods for ventricle volume estimation: Area length (for monoplane LVA and biplane LVA/RVA), Simpson (for monoplane LVA and biplane RVA) and Pyramid (Monoplane RVA).
- Both tools support the same methods for wall motion analysis: Centerline and Slager (LVA only).
- Both tools provide quantification of vessel and ventricle parameters based on semi-automatic analysis of 2D angiographic X-ray images.
- Both tools offer the same workflow: select image – calibrate – measure – correct / adjust – report.
- Both tools provide automatic calibration based on iso-centering
- Both tools provide manual calibration based on known dimensions of catheters, sphere phantoms or user defined reference distance.
- Both tools provide customizable settings for the implemented methods
- Both tools provide a task oriented user interface with guidance instructions

The technological differences between **2D Quantitative Analysis** and the Quantitative Analysis functionality embedded in the currently marketed *Allura Xper FD series and Allura Xper OR Table series* are noted below:

- The Quantitative Analysis functionality of the predicate device supports two additional methods for ventricle volume estimation, the Multiple Slices (Biplane RVA) and Two Chamber (Monoplane RVA) method, which are not supported by **2D Quantitative Analysis**. Philips determined that the three available methods in **2D Quantitative Analysis** are sufficient to support the intended use.
- The Quantitative Analysis functionality of the predicate device supports one additional methods for wall motion analysis, Regional, which is not supported by **2D Quantitative Analysis**. Philips determined that the available methods in **2D Quantitative Analysis** are sufficient to support the intended use.
- **2D Quantitative Analysis** generates a detailed report whereas the Quantitative Analysis functionality of the predicate device provides both a detailed and summary report. The detailed report was considered to be sufficient to support the intended use of **2D Quantitative analysis**.
- **2D Quantitative Analysis** includes an in-application help function with animations which is not available in the Quantitative Analysis functionality of the predicate device.

The differences between the **2D Quantitative Analysis** and the predicate device do not raise any new questions regarding safety or effectiveness. Based on the information provided above, **2D Quantitative Analysis** is substantially equivalent to the currently marketed device in terms of technological characteristics.

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on **2D Quantitative Analysis** and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance documents:

- IEC 62304 Medical device software – Software life cycle processes (Ed. 1.0, 2006),
- IEC 62366 Medical devices – Application of Usability engineering to medical devices (Ed. 1.0, 2007),
- ISO 14971 Medical devices – Application of risk management to medical devices (Ed. 2.0, 2007),
- Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005 (document number 337).
- Guidance for Industry and FDA Staff - Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016 (document number 1757)

Software verification testing has been performed to cover system level requirements as well as risk control measures. Results demonstrated that all executed tests were passed.

Dedicated phantom based algorithm validation testing has been performed to ensure sufficient accuracy and agreement with the predicate device. Results demonstrated that the algorithm confirms to its specifications.

Non-clinical software validation testing covered the intended use and commercial claims as well as usability testing with representative intended users. Results demonstrated that the **2D Quantitative Analysis** conforms to its intended use and user needs.

Therefore, **2D Quantitative Analysis** is substantially equivalent to the currently marketed *Allura Xper FD series and Allura Xper OR Table series* in terms of safety and effectiveness.

Summary of Clinical Performance Data:

2D Quantitative Analysis, did not require clinical data since substantial equivalence to the currently marketed *Allura Xper FD series and Allura Xper OR Table series* was demonstrated with the following attributes:

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

Substantial Equivalence Conclusion:

2D Quantitative Analysis is substantially equivalent to the currently marketed Allura *Xper FD series / Allura Xper OR Table series* containing the embedded Quantitative Analysis functionality in terms of indications for use, technological characteristics and safety and effectiveness.

Additionally, substantial equivalence was demonstrated by non-clinical performance tests provided in this 510(k) premarket notification. These tests demonstrate that **2D Quantitative Analysis** complies with the user needs requirements as well as the requirements specified in the international and FDA-recognized consensus standards. **2D Quantitative Analysis** is as safe and effective as its predicate device and does not raise any new safety and/or effectiveness questions.