



Food and Drug Administration
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Silver Spring, MD 20993-0002

Philips Medical Systems Nederland B.V.
% Ms. Jeanette Becker
Regulatory Affairs Manager
Veenpluis 4-6
Best, 5684 PC
THE NETHERLAND

August 10, 2016

Re: K160147
Trade/Device Name: CT TrueView
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, LLZ
Dated: July 11, 2016
Received: July 14, 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

Indications for Use

510(k) Number (if known)
K160147

Device Name
CT TrueView

Indications for Use (Describe)

CT TrueView assists physicians during cardio-vascular interventions when analyzing 2D images by segmenting a previously acquired 3D CT to create a 3D model of the coronary vessel tree.

CT TrueView supports the physician navigating a catheter or guide wire through the coronary arteries by providing a composite image that combines a 2D X-ray exposure image with a CT based 3D visualization of the heart and/or coronaries.

CT TrueView is suitable for use with the adult human population.

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: January 11, 2016

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

Contact Person: Ms. Jeanette Becker
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Device:

Trade Name:	CT TrueView
Device Name:	CT TrueView
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:

Trade Name:	<i>Allura 3D-CA Release 1</i>
Manufacturer:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K042334 (September 27, 2004)
Classification Regulation:	21 CFR, Part 892.1650
Classification Name:	Image-intensified fluoroscopic x-ray system
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	LLZ (primary), IZI (secondary)

Reference Device:

Trade Name:	<i>CardioCT</i>
Manufacturer:	Shina Systems Ltd.
510(k) Clearance:	K070226 (September 03, 2007)
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 (primary)
 LLZ (secondary)

Device description:

CT TrueView is a software medical device with the following characteristics:

- The proposed CT TrueView is considered an accessory to the currently marketed Allura Xper FD series X-ray System (Philips Medical Systems Nederland B.V., K141979). It operates on the currently marketed Interventional Workspot (Philips Medical Systems Nederland B.V., K121296) software hosting platform.
- The proposed CT TrueView assists physicians during cardio-vascular interventions by providing a 3D model of the coronary vessel tree. The 3D model is created from a pre-acquired 3D CT dataset segmented by the user.
- The proposed CT TrueView supports the physician navigating a catheter or guide wire through the coronary arteries by providing a composite image that combines a 2D X-ray exposure with a CT based 3D visualization of the heart and/or coronaries.
- The proposed CT TrueView provides a range of viewing angles that result in an unobstructed and minimally foreshortened projection of a specific segment and/or bifurcation. The selected viewing angles are programmed automatically on the connected Allura Xper FD series X-ray system.
- The proposed CT TrueView includes measurement tools to estimate the length and diameter of a segment of the 3D model and to estimate the bifurcation angle of a bifurcated segment.
- The proposed CT TrueView provides a CTO Navigator feature that allows the user to combine a 2D X-ray image with the 3D model of the heart and/or coronaries in one composite image.

Indications for Use:

CT TrueView assists physicians during cardio-vascular interventions when analyzing 2D images by segmenting a previously acquired 3D CT to create a 3D model of the coronary vessel tree.

CT TrueView supports the physician navigating a catheter or guide wire through the coronary arteries by providing a composite image that combines a 2D X-ray exposure image with a CT based 3D visualization of the heart and/or coronaries.

CT TrueView is suitable for use with the adult human population.

Technological characteristics:

At a high level, the subject and predicate device are based on the following same technological elements:

- Both are intended to be used in combination with the currently marketed Allura Xper FD series X-ray System (Philips Medical Systems Nederland B.V., K141979). They both have X-ray system integration, can be controlled from the table side of the Allura Xper FD series X-ray system and get input data from the aforementioned Allura Xper FD series X-ray system.
- Both use a segmentation technique to create a 3D model of the coronary tree.
- Both use a cardiac modeling technique to obtain a still 3D model of the heart and /or coronary arteries.
- Both can display data that indicates the lesion length and diameter present in the segment without foreshortening.
- Both allow the physician to determine an optimal projection to visualize a specific vessel segment or bifurcation.
- Both offer visualization tools that allow the physician to manipulate and view the 3D model in different ways.

The following technological differences exist between the subject and predicate device:

- **CT TrueView** has automatic segmentation instead of semi-automatic segmentation. The user can correct the segmentation results.
- **CT TrueView** not only uses 2D images generated by the Allura Xper FD series X-ray system, but also uses previously acquired 3D CT data.
- **CT TrueView** allows the physician to assess and determine the angle of bifurcating vessel branches.
- **CT TrueView** offers curved reformat and cross sections views of the 3D model.
- **CT Trueview** contains an optional CTO Navigator image fusion functionality that provides a static composite image that combines a 2D X-ray angiographic image with the CT based 3D model of the heart and/or coronaries. This static composite reference image assists the physician in navigating the catheter or guide wire through the coronary arteries.

As these differences/additional technological characteristics are considered low risk (only providing further support to the clinicians in performing interventions) and the functionalities were verified and validated with equivalent methods, these differences do not raise new questions on safety or effectiveness.

Therefore, **CT TrueView** is substantially equivalent to the currently marketed predicate device *Allura 3D-CA Release 1* in terms of technological characteristics.

Summary of Non-clinical Performance Data:

Non-clinical performance testing has been performed on **CT TrueView** and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- IEC 62304 Medical device software – Software life cycle processes (Ed. 1.0, 2006),
- IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices (Ed. 1.0, 2015-02),
- 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), and
- 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).

Software verification testing included the following activities:

- Verification of the functional, non-functional and user interface requirements as well as the identified hazard mitigations. Result: all verification tests were executed successfully, showing that the requirements are met and hazard mitigations are implemented correctly.
- Verification of the accuracy of the measurement tool. Result: The accuracy of the measurement tool is in line with its specification.

Software validation testing included the following activities:

- Validation of the intended use and commercial claims. This has been performed via in-house validation. Results show that **CT TrueView** can be used as defined in the Intended Use and the commercial claims.
- Usability validation. The results of the usability analysis indicate that the usability of **CT TrueView** is acceptable.
- Algorithm validation, consisting of two studies:
- Validating the orientation mismatch between the 3D model of an object and the modeled object. This has been done with 3 different phantoms representing a coronary vessel tree, a vessel with an occlusion and a vessel with stenosis.
- Validating the performance of the TrueView tool in determining an optimal projection to visualize a specific vessel segment or bifurcation without foreshortening or overlapping branches.

The results of the two studies show that the algorithms provide the user with correct information required to support the clinical procedure within the scope of the intended use of **CT TrueView**.

All of these tests were used to support substantial equivalence of the subject device. The test results in this 510(k) premarket notification demonstrate that **CT TrueView**:

- complies with the aforementioned international and FDA-recognized consensus standards and FDA guidance document, and
- meets the acceptance criteria and is adequate for its intended use.

Therefore, **CT TrueView Rel. 2.0** is substantially equivalent to the currently marketed predicate device *Allura 3D-CA Release 1* in terms of safety and effectiveness.

Summary of Clinical Performance Data: The subject of this premarket submission, **CT TrueView Rel. 2.0**, did not require clinical studies to support substantial equivalence.

Substantial Equivalence Conclusion: The **CT TrueView Rel. 2.0** software medical device is substantially equivalent to the currently marketed predicate device *Allura 3D-CA Release 1* in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. The (non-)clinical performance tests provided in this 510(k) premarket notification demonstrate that the proposed **CT TrueView Rel. 2.0** is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.