K 132524
Page 1 of 5

PHILIPS

Philips Medical Systems

JUN 13 2014

510(k) Summary

CT TAVI Planning Application

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. General Information

21 CFR 807.92 (a)(1), (2)

Company Name:	Philips Medical Systems (Cleveland), Inc.
Address:	595 Miner Rd Cleveland, Ohio 44143 USA
Contact Person:	Susan Quick
Telephone Number:	440-483-2291
Prepared (date):	2013 June 28
Manufacturing Site:	Philips Medical Systems 9617978 Matam Building 34 Haifa, Israel 31004
Trade Name of Device:	CT T Transcatheter Aortic Valve Implantation AV Planning Application
Classification:	Class II
Regulatory Section:	Computed Tomography X-Ray System and accessories 21 CFR 892.1750
ProCode:	90 JAK

21 CFR 807.92(a) (3): Legally marketed predicate device to which substantial equivalence is claimed:

The CT TAVI Planning Application is comparable in type and substantial equivalence to the legally marketed devices currently in commercial distribution, namely:

1. Predicate Device:	Philips HeartNavigatior
Manufacturer:	Philips Medical Systems Nederland B.V.
Predicate Device k#:	K111245
2. Predicate Device:	Vitrea CT TAVR Planning
Manufacturer:	Vital Images
Predicate Device k#:	K122578

21 CFR 807.92(a) (4): Description of the device that is the subject of this premarket notification:

1. Summary of functions of the device and its major components

The CT TAVI Planning application is intended to be used for patients with aortic valvular disease, severe symptomatic aortic stenosis or tricuspid aortic valve. The intended part of the body for this application is the human heart, specifically the ascending aorta, aortic root, coronary ostia and left ventricle in order to assess the aortic valve in pre-operational planning and transcatheter aortic valve replacement procedures.

CT TAVI Planning is a non-invasive post-processing application providing 3D model-based segmentation of the aortic valve and aortic arch. The CT TAVI Planning application provides assessment and measurements of relevant heart structures for TAVI-device sizing, and allows the user to select a starting angle for C-arm position from the possible optimal positions from the CT TAVI and select a C-arm angle the user feels is appropriate to use in the catheterization laboratory by the Interventional team performing the procedure (to be used during the procedure itself).

The physician retains the ultimate responsibility for making the determination of patient eligibility or which device is implanted based on their standard practices and additional imaging modalities such as echocardiography.

- CT TAVI Planning allows users to select patient CT studies from various vendors.
- CT TAVI Planning requires contrast enhanced CT images.

- CT TAVI Planning provides visualization of aortic valve calcification during the segmentation stage with tissues deselected.
- CT TAVI Planning provides segmentation of the ascending aorta, aortic root, left ventricle and coronary ostia adjusted utilizing an algorithm which can be manually.
- CT TAVI Planning provides detection with manual correction capability of: the annulus plane, Left Ventricular Outflow Tract (LVOT) plane, sinotubular junction plane, sinus of valsalva plane, ascending aorta plane, right coronary cusp landmark, left coronary cusp landmark, non-coronary cusp landmark, right coronary ostium and left coronary ostium.
- CT TAVI Planning provides contour detection with manual correction capability, with diameter, area and distance measurements at each plane as well as distance to each coronary ostia from the annulus plane.
- CT TAVI Planning provides 2D and 3D views.
- Planning provides C-arm angles which can be utilized to determine the best angle for deployment during the procedure.
- CT TAVI Planning provides a 3D display of the ascending aorta and aortic root at the C-arm angle chosen within the application.
- CT TAVI Planning provides tools to generate reports to distribute findings.

21 CFR 807.92(a) (5): Intended Use

The CT TAVI Planning application is intended to be used for patients with aortic valvular disease, severe symptomatic aortic stenosis or tricuspid aortic valve. The intended part of the body for this application is the human heart, specifically the ascending aorta, aortic root, coronary ostia and left ventricle in order to assess the aortic valve in pre-operational planning of transcatheter aortic valve replacement procedures.

CT TAVI Planning is a non-invasive post-processing application providing 3D model-based segmentation of the aortic valve and aortic arch. The CT TAVI Planning application provides assessment and measurements of relevant heart structures for TAVI-device sizing, and allows the user to select a starting angle for C-arm position from the possible optimal positions from the CT TAVI and select a C-arm angle the user feels is appropriate to use in the catheterization laboratory by the Interventional team performing the procedure (to be used during the procedure itself).

The physician retains the ultimate responsibility for making the determination of patient eligibility or which device is implanted based on their standard practices and additional imaging modalities such as echocardiography.

21 CFR 807.92(a) (6): Technological Characteristics:

The CT TAVI Planning Application is intended for visualization, assessment and quantification of medical images, specifically quantitative distance and area measurements for CT images from adult patients with a diagnosis of aortic stenosis in which a non-surgical approach is recommended.
The application supports contrast-enhanced, prospectively ECG-gated axial or retrospectively-gated helical CT images as well as un-gated helical scans.
The application provides visualization and measurement tools for qualitative and quantitative visualization and assessment of the input data.
It provides tools to determine the size and shape of the aortic root anatomy, ascending aorta and left ventricular outflow tract.

The CT TAVI Planning Application provides model-based segmentation of the aortic valve, ascending aorta and left ventricle, detection of the coronary ostia, planes detection and dimensions measurements of the aortic annulus, left ventricular outflow tract, simotubular junction, sinus of valsalva, ascending aorta and distance to coronary ostia for TAVI-device sizing. While both predicate devices and CT TAVI Planning provide detection and manual correction of the annulus plane, Philips CT TAVI Planning, utilizing the same planes and landmarks detection algorithm as Philips HeartNavigator, has extended that functionality to also include additional planes relevant to the planes at which physicians currently measure for pre-planning: Left Ventricular Outflow Tract (LVOT), Sinotubular Junction, Sinus of Valsalva, and Ascending Aorta planes.

21 CFR 807.92(b) (1): Brief discussion of nonclinical tests submitted, referenced or relied on in this premarket notification:

Verification was conducted to provide objective evidence that the application met its design specifications. This was done by testing the function and implementation of the application as well as risk management file.

The narrative below provides a brief summary of the verification and validation activities. The details of the testing including test plans and reports can be found in [TAVI-008] – Verification of the 510(k).
The verification plan for the TAVI Application (TAVI-007) outlines the verification activities conducted to verify the function of the application and product's stability. Testing included full functionality of TAVI application and risk management file (RMF) related to defined requirements. The requirements for TAVI planning are traced to the clinical DRS and detailed test scenarios were written and accordingly the verification was conducted [TAVI-005]. TAVI verification included sanity tests which gave an overview of the application maturity for each build, critical tests which included tests of the main features and workflow and RMF tests which in general check calculations, measurements, patient details and information and other scenarios which might lead to misdiagnosis. Full functionality test included all TAVI functionality cases and covered all of the detailed requirements which provided us with assurance that the tested features work as required. Verification also covered the defect fixes of TAVI.

All the planned activities for verification have been completed and there are no blocking

defects for beta phase.

21 CFR 807.92(b) (2): Brief discussion of clinical tests submitted, referenced or relied on in this premarket notification:

The TAVI validation activities, as documented in the TAVI Validation Plan (TAVI-009), were performed in the following two ways to provide objective evidence that the TAVI Software Application meets the intended use and defined customer needs as documented in the Customer Requirement Specification (CRS) (ISP-600-P1,2-0002-01):

1) Internal validation in a non-hospital environment by clinical experts
Clinical experts can be non-Philips or Philips employees that can simulate the work of a typical clinical user as long as they did not participate in the development process and verification process Validation will be done in Philips facilities using nominal systems or outside Philips on a laptop which meets the HW requirements (evidence in ISP-600-P5-0109-01, Using Portal Demo laptops for IntelliSpace Portal validation; and clinical expert report as part of the Verification Report ISP-600-P5-0093-01

2) External validation at beta sites
System is installed in a hospital environment and used by the local medical staff (radiologists and/or cardiologists).

The results of the two validation activities found in the Validation Report for Transcatheter Aortic Valve Implantation (TAVI-0010) confirms that the TAVI software application meets user needs and intended uses.

21 CFR 807.92(b) (3): The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a) (3) of this section:

The nonclinical and clinical tests have demonstrated that the device is safe and works according its intended use.

The CT TAVI Planning Application does not introduce new indications for use, nor does the use of the device result in any new potential hazard. Philips Medical Systems considers CT TAVI Planning Application to be substantially equivalent to the Philips HeartNavigator (K111245) and the Vital Images Vitrea CT TAVR Planning (K133578).

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

June 13, 2014

Philips Medical Systems
% Ms. Susan Quick
Regulatory Affairs Specialist
595 Miner Road
CLEVELAND OH 44143

Re: K132524
Trade/Device Name: CT Transcatheter Aortic Valve Implantation (TAVI) Planning Application
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: May 13, 2014
Received: May 15, 2014

Dear Ms. Quick:

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,

Robert A Ochs

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)*
K132524

Device Name
CT TAVI Planning Application

Indications for Use *(Describe)*
The CT TAVI Planning application is intended to be used for patients with aortic valvular disease, severe symptomatic aortic stenosis or tricuspid aortic valve. The intended part of the body for this application is the human heart, specifically the ascending aorta, aortic root, coronary ostia and left ventricle in order to assess the aortic valve in pre-operational planning of transcatheter aortic valve replacement procedures.

CT TAVI Planning is a non-invasive post-processing application providing 3D model-based segmentation of the aortic valve and aortic arch. The CT TAVI Planning application provides assessment and measurements of relevant heart structures for TAVI-device sizing, and allows the user to select a starting angle for C-arm position from the possible optimal positions from the CT TAVI and select a C-arm angle the user feels is appropriate to use in the catheterization laboratory by the Interventional team performing the procedure (to be used during the procedure itself).

The physician retains the ultimate responsibility for making the determination of patient eligibility or which device is implanted based on their standard practices and additional imaging modalities such as echocardiography.

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)*

Robert A Ochs

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."