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

September 25, 2014

Philips Medical Systems
% Ms. Susan Quick
Regulatory Affairs Specialist
Philips Medical Systems (Cleveland), Inc.
595 Miner Road
CLEVELAND OH 44143

Re: K133603
Trade/Device Name: Philips CT Dynamic Myocardial Perfusion (DMP) Application
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 15, 2014
Received: September 16, 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,

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)*
K133603

Device Name
Philips CT Dynamic Myocardial Perfusion (DMP) Application

Indications for Use *(Describe)*
The CT Dynamic Myocardial Perfusion (CT DMP) application is intended to assist clinicians in the visualization and diagnostic assessment of cardiac images focusing on the left ventricular myocardium: specifically providing qualitative myocardial blood flow measurements for CT images. The application supports axial, ECG gated CT images, consisting of multiple time shots within the same study of the same myocardial region overtime (i.e., dynamic CT scans), after the injection of intravenous contrast. The application displays the results as a composite (single image that is calculated from a set of time course images at a single location) image.

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)*

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

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510(k) Summary

CT DMP Application

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

1. 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 Oct 25
Manufacturing Site:	Philips Medical Systems PO Box 325 Matam Building 34 Haifa, Israel 31004

2.

Trade Name:	CT Dynamic Myocardial Perfusion (DMP) Application
Common Name:	Accessory to Computed Tomography X-Ray System
Classification:	Class II
Regulatory Section:	Sec. 892.1750 Computed Tomography X-Ray System
ProCode:	90JAK

3. Predicate Device Information:

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

1. Predicate Device: Philips Brain Perfusion

   Manufacturer: Philips Medical Systems (Cleveland), Inc.

   Predicate Device k#: K033677

2. Predicate Device: CardioCT

   Manufacturer: Shina

   Predicate Device k#: K070226

3. Predicate Device: Philips Brilliance Volume

   Manufacturer: Philips Medical Systems (Cleveland), Inc.

   Predicate Device k#: K060937

4. Device Description:

Summary of functions of the device and its major components

The CT Dynamic Myocardial Perfusion (DMP) Application is intended for visualization and assessment of cardiac images focusing on the left ventricular myocardium: specifically providing qualitative myocardial blood flow measurements for CT images. The application supports axial, ECG gated CT images, consisting of multiple time shots within the same study of the same myocardial region over time. The application provides visualization and measurement tools for qualitative visualization and assessment of the input data. The data upon loading is first registered and filtered in the spatial and the temporal domain to reduce any noise variations, following which, the cardiac axes of the heart are detected using the automatic and manual tools. The images are displayed in the short-axis format and the clinician can then define the regions of interest using manual tools upon the short axis format. The software calculates measurements of myocardial blood flow, myocardial blood volume, time to peak, and peak enhancements, and provides tools for the clinician to assess these results. The user may save the results. The clinician retains the ultimate responsibility for making the pertinent assessment based on their standard practices and visual assessment of the myocardial perfusion CT images. The qualitative assessment is to be used in conjunction with traditional visual assessment of CT images for the assessment of coronary artery disease.

The different components in the CT DMP application are:

- CT DMP Models:
- CT DMPViewingModel - Main model in the application. Holds all the relevant data for results: volume, tissue, etc.

CT DMP Algorithms:

- Artery Automatic Detection
- Segmentation
- Cardiac Axes
- Spatio-temporal filtering
- Perfusion Maps Calculation

CT DMP Controllers:

- DMPBackgroundProcessing - Used for activating long operations on a different thread
- DMPBatchController - Creation of a combined spatial-temporal batch and cine
- ECGController – Used for showing ECG options.

CT DMP Tools:

- DMPSegmentationCorrectionTool
- AxesCorrectionTool
- ROITool

5. Indications for Use

The CT Dynamic Myocardial Perfusion (CT DMP) application is intended to assist clinicians in the visualization and diagnostic assessment of cardiac images focusing on the left ventricular myocardium: specifically providing qualitative myocardial blood flow measurements for CT images. The application supports axial, ECG gated CT images, consisting of multiple time shots within the same study of the same myocardial region over time (i.e., dynamic CT scans), after the injection of intravenous contrast. The application displays the results as a composite (single image that is calculated from a set of time course images at a single location) image.

6. Comparison to Predicate

The CT DMP application, Philips Brain Perfusion, and the Philips Brilliance Volume (Functional CT) all generate perfusion results including blood volume, blood flow, time-to-peak and mean transit time from dynamic (serial) CT scans. The Brilliance Volume Functional CT application is built to process serial CT datasets of the body while the CT DMP application processes ECG-gated serial CT datasets of the heart and myocardium; the underlying algorithm (Mullani-Gould formulation) is the same. Additionally, the segmentation and the cardiac axes generation used in the CT DMP are similar to the one implemented in Shina CardioCT.

Conclusion:
The Philips CT DMP application is similar to the predicate devices listed above, Philips Brain Perfusion, Philips Brilliance Volume, Shina CardioCT which have been cleared through premarketing notification. There are no significant differences between Philips CT DMP and the other predicate devices that may raise new issues of safety or effectiveness.

7. Safety

The Philips CT DMP application is manufactured in accordance with the Quality System Regulation (QSR) 21 CFR 820 and to International Standards ISO 13485:2003. Potential hazards are identified in a hazard analysis and controlled in the following manner: Software: Safety is assured by the company procedures that conform to accepted practices, including the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Instructions for Use are provided with the software application for the safe and effective operation of the application by the user.

8. Performance Testing Summary

Verification Activities:
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 Section 018 of this submission.

The verification plan for the CT DMP Application (DMP-007) outlines the verification activities conducted to verify the function of the application and product's stability. Testing included full functionality of CT DMP application and risk management file (RMF) related to defined requirements. The requirements for CT DMP are traced to the clinical DRS and detailed test scenarios were written and accordingly the verification was conducted [DMP-005]. CT DMP 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. CT DMP Algorithm implementation was evaluated through a direct comparison of values obtained by comparing the performance of CT DMP and the Philips predicate, Brilliance Volume K060987, under the same use conditions. The values obtained in the comparison were similar or the same under all test conditions.

Full functionality testing included all CT DMP 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 CT DMP.

All the planned activities for verification have been completed.

Validation Activities:
The CT DMP validation activities, as documented in the DMP Validation Plan (DMP-009), were performed to provide objective evidence that the CT DMP Application meets the intended use and defined customer needs outlined in the DRS DMP-002.

Validation was performed externally to Philips on a laptop which met the HW requirements. The results of the validation activities found in the Validation Report for DMP (DMP-0010) confirms that the CT DMP Application meets user needs and intended uses.

Based on the above considerations, it is Philips's opinion that the results of the verification and validation testing and the results of the risk analysis demonstrates safety and effectiveness of the Philips CT DMP Application and that it is substantially equivalent to the predicate devices documented above.

Information on security and privacy attributes of the CT DMP Application are found in document ISP-600-P3-0021-01 which can be found in Section 021.