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

Philips Medical Systems Nederland B.V.
% Mr. Yoram Levy
QA/RA Consultant
Qsite
31 Haavoda St.
Binyamina, 30500
ISRAEL

December 19, 2016

Re: K162955
Trade/Device Name: Multi-Modality Tumor Tracking (MMTT) application
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 19, 2016
Received: October 24, 2016

Dear Mr. Levy:

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 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)*
K162955

Device Name
Multi-Modality Tumor Tracking (MMTT) application

Indications for Use *(Describe)*
Multi-Modality Tumor Tracking (MMTT) application is a post processing software application used to display, process, analyze , quantify and manipulate anatomical and functional images, for CT, MR PET/CT and SPECT/CT images and/or multiple time-points. The MMTT application is intended for use on tumors which are known/confirmed to be pathologically diagnosed cancer. The results obtained may be used as a tool by clinicians in determining the diagnosis of patient disease conditions in various organs, tissues, and other anatomical structure.

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)*

PHILIPS

510(K) SUMMARY

Multi-Modality Tumor Tracking (MMTT) application

Date prepared: October 19, 2016

I. Submitter's name and address

Establishment name:	Philips Medical Systems Nederland B.V.
Establishment address:	Veenpluis 4-6 5684 PC Best The Netherlands
Establishment registration:	3003768277
Primary Contact person:	Yoram Levy, Qsite QA/RA Consultant 31 Haavoda Street Binyamina, Israel 30500 Tel +(972)4-638-8837; Fax (972)4-638-0510 Yoram@qsitemed.com
Alternative contact person	Mr. Yonel Braunstein Head of Regulatory and Clinical Affairs Philips Medical Systems Nederland B.V E-mail: Yonel.Braunstein@philips.com

II. Device information

Trade name:	***Multi-Modality Tumor Tracking (MMTT)*** application
Device Classification Name	System, Image processing, Radiological
Device Class	Class II
Classification Panel	LLZ
Product Code	Radiological Image Processing Software
Regulation Description	21 CFR 892.2050

III. Device Description:

Philips Medical Systems' ***Multi-Modality Tumor Tracking (MMTT)*** application is a post - processing software. It is a non-organ specific, multi-modality application which is intended to function as an advanced visualization

application. The MMTT application is intended for displaying, processing, analyzing, quantifying and manipulating anatomical and functional images, from multi-modality of CT ,MR PET/CT and SPECT/CT scans.

The ***Multi-Modality Tumor Tracking (MMTT)*** application allows the user to view imaging, perform segmentation and measurements and provides quantitative and characterizing information of oncology lesions, such as solid tumor and lymph node, for a single study or over the time course of several studies (multiple time-points). Based on the measurements, the MMTT application provides an automatic tool which may be used by clinicians in diagnosis, management and surveillance of solid tumors and lymph node, conditions in various organs, tissues, and other anatomical structures, based on different oncology response criteria.

Key Features

The MMTT application has the following key features:

1. Longitudinal follow-up for oncology.
2. Multi-modality support: CT ,MR PET/CT and SPECT/CT scans
3. Load up multiple concurrent studies for temporal measurements
4. Automatic and manual registration between studies and between series within study (same patient, different time-point).
5. Identify pre-defined data types (pre-sets) and user created hanging layouts.
6. Semi-automatic and manual volumetric tissue segmentation and editing tools.
7. Findings management of the identified lesions (lesion properties, Join, Match, un-match, delete)
8. Automatic software calculation of the following measurements for each segmented lesion:
    - Long Axis- Longest diameter on an axial slice, between two points on the lesion contour in 2D dimensions found in the segmented volume (mm)
    - Short axis (mm) - Longest diameter found perpendicular to Long Axis in the same axial 2D slice.
    - Long axis x short axis- the multiplication result of the longest diameter in axial slice with the short diameter of the same slice

- Max 3D diameter (mm)- longest diameter that can be drawn in the 3D volume
- Lesion Volume (cm^3)
- Max Area (cm^2)- maximal area of lesion on an axial slice in the volume
- Mean/Max/Min/SD values of all functional volumes
- Doubling time (days)- the time it takes for the volume to double
- Density- the mean density of all target tumor (only for CT data)
- Enhanced volume/Enhanced Percentage/Enhanced Mean/Enhanced SD (available only for qEASL preset).

9. Support oncology response criteria such as RECIST 1.0, RECIST 1.1, WHO, CHOI, PERCIST, irRC, mRECIST, qEASL.
10. Support SUV calculation for PET scans, such as: SUV Body Weight (the default option); SUV Lean Body Mass; SUV Body Surface Area; and SUV Body Mass Index
11. Results displayed in tabular and graphical formats.
12. Export results in many formats.

IV. Intended use:

Multi-Modality Tumor Tracking (MMTT) application is a post processing software application used to display, process, analyze, quantify and manipulate anatomical and functional images, for CT, MR PET/CT and SPECT/CT images and/or multiple time-points. The MMTT application is intended for use on tumors which are known/confirmed to be pathologically diagnosed cancer. The results obtained may be used as a tool by clinicians in determining the diagnosis of patient disease conditions in various organs, tissues, and other anatomical structures.

V. Predicate Devices:

The following table shows the predicate devices of the proposed Philips Medical Systems ***Multi-Modality Tumor Tracking (MMTT)***:

Table No. 2-1: Identification of Predicate Devices

	Device Name	Manufacturer	510k No	Date of Clearance
Primary predicate	Syngo TrueD	Siemens Medical Solution	K101749	August 16, 2010
Predicate	EBW NM 2.0 TT	Philips Medical Systems	K111336	May 24, 2011

The proposed Philips Medical Systems ***Multi-Modality Tumor Tracking (MMTT)*** and its predicate devices, syngo TrueD (K101749) and EBW NM 2.0 (K111336), are substantially equivalent in regards to its intended use, clinical indications, principle of operation and fundamental technology principles.

Further to the predicate devices, Philips has identified the following currently marketed devices as reference predicate devices of proposed ***Multi-Modality Tumor Tracking (MMTT)***:

Table 2-2: Identification of MMTT application Reference Devices

Device Name	Manufacturer	510k No	Date of Clearance
syngo.MR Neurology and syngo.MR Oncology	Siemens AG	K151353	April 8, 2016
syngo. Via	Siemens AG	K123920	Jan 18 2013
Myrian 1.11	Myrian	K113620	July 13, 2012
I4 (Integrated Intelligent Imaging Informatics) system	Philips Medical System	K160315	Feb 19, 2016
sTT under Spectral CT Applications	Philips Medical System	K150665	August 7, 2015
Lung Nodule Assessment and Comparison Option	Philips Medical System	K023785	Feb 10 2003

The syngo.MR Neurology and syngo.MR Oncology (K151353), syngo. Via (K081426), Myrian 1.11 (K123920), I4 (Integrated Intelligent Imaging Informatics) system (K160315), sTT under Spectral CT Applications

(K150665) and Lung Nodule Assessment and Comparison Option (K023785) are reference devices for additional technologies and support the additional application functionalities and enhanced capabilities.

VI. Substantial Equivalence to Predicate Devices

Feature	The proposed device: Multi-Modality Tumor Tracking (MMTT)	Primary Predicate: syngo TrueD (K101749)	Predicate: EBW NM 2.0 TT (K111336)
Device Classification Name	System, Image processing, Radiological	System, Image processing, Radiological	System, Image processin Radiological
Device Class	Class II	Class II	Class II
Classification Panel	Radiology	Radiology	Radiology
Product Code	LLZ	LLZ	90 JAK
Regulation Description	Picture Archiving and communication system	Picture Archiving and communication system	Picture Archiving and communication system
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050
Intended users	Radiologists and Technologist	Radiologists, Technologist	Radiologists and Technologist
Type of scans	CT ,MR PET/CT and SPECT/CT	CT ,MR PET/CT and SPECT/CT	Nuclear scans
Intended Body part	All body	All body	All body
Type of scans	Multi-Modality support: CT ,MR PET/CT and SPECT/CT	Multi-Modality support: CT ,MR PET/CT and SPECT/CT	Multi-Modality supports PET/CT and SPECT/CT
Loading multiple studies	Yes.	Yes	Yes
3D image review	Yes	Yes	Yes
3D comparative review	Yes	Yes	No
Automatic image registration and synchronization	Yes	Yes	No

Feature	The proposed device: Multi-Modality Tumor Tracking (MMTT)	Primary Predicate: syngo TrueD (K101749)	Predicate: EBW NM 2.0 TT (K111336)
Matching and propagation of lesions	Yes	NO	Yes
Semi-Automatic and manual Lesion segmentation	Yes	Yes	Yes
Segmentation editing tools	Yes	Yes	Yes
Printing Option	Yes	Yes	Yes
DICOM	Yes	Yes	Yes

The proposed Philips Medical Systems ***Multi-Modality Tumor Tracking (MMTT)*** and the identified predicate devices, primary- syngo TrueD (K101749) and predicate- and EBW NM 2.0 (K111336) are substantially equivalent in terms of indication for use and intended users, design features, principle of operation and fundamental scientific technology, and safety and/or effectiveness.

In conclusion, Philips believes that the proposed ***Multi-Modality Tumor Tracking (MMTT)*** does not introduce any new potential safety and/or effectiveness issues and is substantially equivalent to the identified predicate devices, primary- syngo TrueD (K101749) and predicate- and EBW NM 2.0 (K111336).

VII. Brief discussion of the nonclinical tests submitted, referenced or relied on

No performance standards for PACS systems or components have been issued under the authority of Section 514. Non-clinical performance testing has been performed on ISPP and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance document:

- ISO 14971 Medical devices – Application of risk management to medical devices
- IEC 62304 Medical device software – Software life cycle processes
- IEC 62366-1 Medical devices – Part 1:Application of usability engineering to medical devices
- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- DICOM PS 3.1-3.18 standard Digital Imaging and Communications in Medicine (DICOM) Standard

Philips Medical Systems ***Multi-Modality Tumor Tracking (MMTT)*** application was tested in accordance with Philips verification and validation processes. Verification and Validation tests have been performed to address intended use, the technological characteristics claims, requirement specifications and the risk management results.

The test results in this 510(k) premarket notification demonstrate that ***Multi-Modality Tumor Tracking (MMTT)***:

- 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 and specifications.

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VIII. Brief discussion of clinical tests submitted, referenced or relied on

The subject of this premarket submission, ***Multi-Modality Tumor Tracking (MMTT)*** application did not require clinical studies to support equivalence.

IX. The conclusions drawn from the nonclinical and clinical tests

Verification and Validation (V&V) activities required to establish performance and functionality of ***Multi-Modality Tumor Tracking (MMTT)*** were performed. Testing performed demonstrated the ***Multi-Modality Tumor Tracking (MMTT)*** meets all defined functionality requirements and performance claims.

X. Overall conclusion:

The ***Multi-Modality Tumor Tracking (MMTT)*** is substantially equivalent to the identified predicate devices, primary- syngo TrueD (K101749) and the predicate device EBW NM 2.0

(K111336) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness. Additionally, verification and validation testing demonstrate the safety and efficacy of the device to meet its intended use and specifications.

Philips Medical believes that the proposed device***, Multi-Modality Tumor Tracking (MMTT)*** application, is substantially equivalent to its identified predicate device and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.