December 12, 2017

Philips Medical Systems Nederland B.V.
% Yoram Levy
Qsite General Manager
Qsite
31 Haavoda Street
Binyamina 30500
ISRAEL

Re: K173467
Trade/Device Name: Advanced Diffusion Analysis (ADA) application
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 2, 2017
Received: November 8, 2017

Dear Yoram 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*
K173467

Device Name
Advanced Diffusion Analysis (ADA) application

Indications for Use *(Describe)*
The Philips Medical Systems' Advanced Diffusion Analysis (ADA) application is a post processing software application to be used by trained professionals including but not limited to physicians and medical technicians. The Philips Medical Systems' Advanced Diffusion Analysis (ADA) application can be used to perform image viewing, process and analysis of MRI Diffusion Weighted Images (DWI).

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.

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:

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"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."

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510(K) SUMMARY

Advanced Diffusion Analysis (ADA) application

Date prepared: November 2, 2017

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	Anat Hersch Regulatory Affairs Lead, ICAP Philips Medical Systems Nederland B.V E-mail: anat.hersch@philips.com

II. Device information

Trade name:	Advanced Diffusion Analysis (ADA)
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

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III. Device Description:

Philips Medical Systems' Advanced Diffusion Analysis (ADA) application is a post-processing software to be used as an advanced visualization application of diffusion MRI medical images. The ADA application is intended to perform image viewing, process and analysis of MRI Diffusion Weighted Images (DWI).

The ADA application can display images acquired at different b-values, where the b-value is a factor that reflects the strength and timing of the gradients used to generate Diffusion-Weighted Images. The ADA application provides advanced supportive analysis and visualization tools of diffusion MRI images and parametric maps, which can be used by the physician for further analysis.

The physician retains the ultimate responsibility for making the final diagnosis.

Key Features

ADA application has the following key features:

1. Support visualization and processing of isotropic diffusion-weighted MRI data.
2. Calculate and display a computed Diffusion Weighted Image (cDWI) at a b-value of choice.
3. Support input image registration in a pre-processing step.
4. Present a default analysis model based on the available original DWI images and provide a selection of alternative available models.
5. Provide diffusion analysis models, as well as parametric maps of Perfusion fraction (f), Pseudo Diffusion coefficient (D*), Diffusion coefficient (D) and Kurtosis (K).
6. Provide a 'Goodness of fit' map, 'Goodness of fit' value and fitted curve showing the fitting quality of the selected model.
7. Display parameter values from user defined ROI's (Regions of Interest).
8. Display the ROI results in tabular and graphical formats.
9. Support export of the parametric maps as grayscale or RGB images for visualization in other viewers or PACS systems.

[V. Intended use:

The Philips Medical Systems' Advanced Diffusion Analysis

(ADA) application is a post processing software application to be used by trained professionals including but not limited to physicians and medical technicians. The Philips Medical Systems' Advanced Diffusion Analysis (ADA) application can be used to perform image viewing, process and analysis of MRI Diffusion Weighted Images (DWI).

V. Predicate Devices:

The ***Advanced Diffusion Analysis (ADA) application*** is substantially equivalent to the following market-cleared devices:

Table 2-1 Predicates table

	Device Name	**Manufacturer**	**510k No**	**Date of Clearance**
Primary predicate	Olea Sphere V3.0	Olea Medical	K152602	March 3, 2016

The proposed Philips Medical Systems Advanced Diffusion Analysis (ADA) application and its predicate device, Olea Sphere V3.0 (K152602) are substantially equivalent in regards to their intended uses, clinical indications, principle of operation and fundamental technology principles.

VI. Substantial Equivalence to Predicate Devices

Feature	The proposed device: Advanced Diffusion Analysis (ADA) application	Primary Predicate: Olea Sphere V3.0 (K152602)
Device Classification Name	System, Image processing, Radiological	System, Image processing, Radiological
Device Class	Class II	Class II
Classification Panel	Radiology	Radiology
Product Code	LLZ	LLZ
Regulation Description	Picture Archiving and communication system	Picture Archiving and communication system
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
Indication for Use	The Philips Medical Systems' Advanced Diffusion Analysis (ADA) application is a post processing software application to be used by trained professionals including but not limited to physicians and medical technicians. The Philips Medical Systems' Advanced Diffusion Analysis (ADA) application can be used to perform image viewing, processing and analysis of MRI Diffusion Weighted Images (DWI).	Olea Sphere V3.0 is **an image processing software package to be used by trained professionals including, but not limited to, physicians and medical technicians**. The software runs on a standard "off-the-shelf" workstation and can be used to perform image viewing, processing, image collage and analysis of medical images. Data and images are acquired through DICOM compliant imaging devices and modalities. **Olea SphereV3.0 provides both viewing and analysis capabilities of functional and dynamic imaging datasets acquired with MRI or other relevant modalities, including a Diffusion Weighted MRI (DWI)** / Fiber Tracking Module and a Dynamic Analysis Module (e.g., dynamic exogenous or endogenous contrast enhanced imaging data for MRI and CT). **The DWI Module is used to visualize local water diffusion**

		properties from the analysis of diffusion-weighted MRI data. The Fiber Tracking feature utilizes the directional dependency of the diffusion to display the white matter structure in the brain or more generally the central nervous system. The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast while repeating acquisitions (e.g., over time with or without variable acquisition parameters) where such techniques are useful or necessary. This functionality is referred to as: Perfusion Module – the calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Permeability Module – the calculation of parameters related to leakage of injected contrast material from intravascular to extracellular space. Arterial Spin Labeling (ASL) Module - the calculation of parameters related to tissue flow based on a MR technique using the water in arterial blood as endogenous tracer to evaluate the perfusion. Relaxometry Module – the calculation of parameters related to the MR longitudinal and transversal relaxation time and rate. Metabolic Module – the calculation of parameters related to the fat signal fraction based on a MR technique using opposed-phase imaging
Intended users	Trained professionals including but not limited to physicians and medical technicians.	Trained professionals including but not limited to physicians and medical technicians.

Intended Body part	All body	All body
Type of scans	Diffusion MRI scans	Multi-Modality support: CT ,MRI PET/CT and SPECT/CT. The DWI Module is for Diffusion MRI scans
Visualization MRI data capabilities	Yes Supports visualization and processing of isotropic diffusion-weighted MRI data	Yes Supports visualization and process isotropic diffusion-weighted MRI data
Display images capabilities	Yes Display images acquired at different diffusion gradient factors (b-values)	Yes Display images acquired at different diffusion gradient factors (b-values)
Image Registration	Yes	Yes
Computed Diffusion Weighted Image (cDWI)	Yes Calculate and display a computed Diffusion Weighted Image (cDWI) at a b-value of choice.	Yes Calculate and display a computed Diffusion Weighted Image (cDWI) at a b-value of choice.
Computed simple ADC Diffusion maps	Yes	Yes
Different diffusion models	Yes The application suggests a selection of diffusion models.	Yes
Region of Interest	Yes The user can select and draw the Region of Interest	Yes The user can select and draw the Region of Interest
Computation of Pseudo-diffusion coefficient (D*) parametric map	Yes	Yes
Computation of diffusion coefficient (D) parametric map	Yes	Yes
Computation of perfusion fraction (f) parametric map	Yes	Yes

Computation of Kurtosis (K) parametric map	Yes	Yes
Computation of goodness of fit parametric map	Yes Provide a 'Goodness of fit' map, 'Goodness of fit' value and fitted curve showing the fitting quality of the selected model.	No
Result	Display results in tabular and graphical format	Display results in tabular and graphical format
Export image Option	Yes	Yes
DICOM format communication	Yes	Yes

The Philips Medical Systems **Advanced Diffusion Analysis (ADA)** and the identified predicate Olea Sphere V3.0 (K152602) are substantially equivalent in terms of indications 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 Advanced Diffusion Analysis (ADA) does not introduce any new potential safety and/or effectiveness issues and is substantially equivalent to the identified predicate devices, Olea Sphere V3.0 (K152602).

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

Non-clinical performance testing has been performed on ADA 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
- Guidance for Industry and FDA Staff – Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

- NEMA PS 3.1-3.20 standard Digital Imaging and Communications in Medicine (DICOM) Standard

Philips Medical Systems **Advanced Diffusion Analysis (ADA)** 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 **Advanced Diffusion Analysis (ADA)**

- 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, **Advanced Diffusion Analysis (ADA)** 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 **Advanced Diffusion Analysis (ADA)** were performed. Testing performed demonstrated the **Advanced Diffusion Analysis (ADA)** meets all defined functionality requirements and performance claims.

X. Overall conclusion:

The **Advanced Diffusion Analysis (ADA)** is substantially equivalent to the identified predicate device, Olea Sphere V3.0 (K152602) 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**, Advanced Diffusion Analysis (ADA)**

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.