DOSIsoft
% Mr. Luc Diot
Quality Director
45/47, Avenue Carnot
Cachan, 94230
FRANCE

March 6, 2019

Re: K182966
Trade/Device Name: PLANET Onco Dose
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: February 8, 2019
Received: February 21, 2019

Dear Mr. Diot:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Michael D. O'Hara 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

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182966

Device Name
PLANET Onco Dose

Indications for Use *(Describe)*
PLANET Onco Dose is a standalone software intended to be used with PET or SPECT hybrid imaging systems in order to manage, process, display and analyze nuclear medicine and other digital medical image series, to assist in medical diagnosis, to assist in treatment analysis and in therapy response assessment, to assist in the contouring of region of interest for radiotherapy.

PLANET Onco Dose is dedicated to be used by qualified medical professionals in Molecular Imaging, and/or Medical Oncology.

The medical modalities of these medical imaging systems include CT, MRI, SPECT, PET, XA, RT Struct and RT Dose as supported by ACR/NEMA DICOM 3 standard format.

PLANET Onco Dose provides the user with the means to segment structures in medical image volumes by providing dedicated delineation, contouring and propagation tools for both tumors and normal tissues (i.e. Regions of Interest (ROI)).

PLANET Onco Dose provides tools to display, co-register (including deformable registration), compute Standardized Uptake Value (SUV) and import / export results (contours and dosimetries) to / from Treatment Planning Systems (TPS) and PACS devices for assessment and response of patients undergoing a course of oncology treatment.

PLANET Onco Dose provides the user with the means to assist in the assessment quantification and verification of radiation doses received by tissues as a result of administering a radionuclide (e.g. Permanent Yttrium-90 microsphere implants).

PLANET Onco Dose provides tools for post-treatment absorbed dose calculation and evaluation on PET and SPECT images. The following functions are available to allow dose calculations for patients after they have received a treatment using permanent Yttrium-90 (Y90) microspheres:
- 3D liver-lung shunt assessment;
- Local Deposition Model;
- Voxel S Value approach based on the schema in MIRD Pamphlet 17 [1];
- Dosimetry based on 90Y-microspheres-PET (or SPECT Bremsstrahlung) series;
- Compatible with PET images acquired with another radioisotope instead of Y90 when Y90 acquisitions are not supported by the scanner (correction of branching ratio and decay parameters).

For Y90 microspheres, PLANET Onco Dose cannot be used to prescribe the radionuclide activity to be administered to the patient for the therapy. The user has to provide the radionuclide parameters (e.g. activity) in order for PLANET Onco Dose to estimate the radiation doses that the tissues received as a result of the administration.
PLANET Onco Dose should only be used for the retrospective determination of dose and not for the case where there is a need for retreatment using Y90 microspheres.

[1] Bolch WE et al. MIRD pamphlet no. 17: the dosimetry of nonuniform activity distributions-Radionuclide S values at the voxel level. J Nucl Med, 1999, 40:11S-36S

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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Premarket Notification 510(k) Summary

[as required by 21 CFR 807.92]

510(k) Summary

K182966

1. Date the Summary was prepared: 2018-10-17

2. Submitter:

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Phone No.:	+33 1 41 24 26 26
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Contact Name:	Mr. Marc USZYNSKI

3. Device Information:

Proprietary Name:	PLANET Onco Dose
Trade Names:	PLANET Onco, PLANET Dose, PLANET Onco Dose
Common Name:	Medical Imaging Software
Classification Name:	System, Image Processing, Radiological (21 CFR 892.2050, Class II, Product Code LLZ)

4. Predicate Device:

K173636 – Velocity – Varian Medical Systems, Inc.

Executive Summary

5. Product Description:

PLANET Onco Dose is a software platform dedicated to medical diagnosis aid, therapy response assessment aid, contouring for radiotherapy and internal dosimetry computation, using molecular imaging modalities.

PLANET Onco Dose is a modular software suite composed of three elements:

- **PLANET**: Core System: license controller, reviewing of multi-modal molecular image series (PET/CT, SPECT/CT, PET/MRI, SPECT/MRI): fusion and registration;
- **PLANET Onco**: Oncology Module: contouring of region of interest, tumor segmentation, tumoral activity monitoring, therapy response assessment;
- **PLANET Dose**: Dosimetry Module: internal dosimetry computation for the Targeted Radionuclide Therapy (TRT).

6. Intended Use and User profiles:

PLANET Onco Dose is a standalone software intended to be used with PET or SPECT hybrid imaging systems in order to manage, process, display and analyze nuclear medicine and other digital medical image series, to assist in medical diagnosis, to assist in treatment analysis and in therapy response assessment, to assist in the contouring of region of interest for radiotherapy.

PLANET Onco Dose is dedicated to be used by qualified medical professionals in Molecular Imaging, and/or Medical Oncology.

The medical modalities of these medical imaging systems include CT, MRI, SPECT, PET, XA, RT Struct and RT Dose as supported by ACR/NEMA DICOM 3 standard format.

PLANET Onco Dose provides the user with the means to segment structures in medical image volumes by providing dedicated delineation, contouring and propagation tools for both tumors and normal tissues (i.e. Regions of Interest (ROI)).

PLANET Onco Dose provides tools to display, co-register (including deformable registration), compute Standardized Uptake Value (SUV) and import / export results (contours and dosimetries) to / from Treatment Planning Systems (TPS) and PACS devices for assessment and response of patients undergoing a course of oncology treatment.

PLANET Onco Dose provides the user with the means to assist in the assessment quantification and verification of radiation doses received by tissues as a result of administering a radionuclide (e.g. Permanent Yttrium-90 microsphere implants).

PLANET Onco Dose provides tools for post-treatment absorbed dose calculation and evaluation on PET and SPECT images. The following functions are available to allow dose calculations for patients after they have received a treatment using permanent Yttrium-90 (Y90) microspheres:

- 3D liver-lung shunt assessment;
- Local Deposition Model;
- Voxel S Value approach based on the schema in MIRD Pamphlet 17 [1];
- Dosimetry based on ^{90}Y-microspheres-PET (or SPECT Bremsstrahlung) series;
- Compatible with PET images acquired with another radioisotope instead of Y90 when Y90 acquisitions are not supported by the scanner (correction of branching ratio and decay parameters).

For Y90 microspheres, PLANET Onco Dose cannot be used to prescribe the radionuclide activity to be administered to the patient for the therapy. The user has to provide the radionuclide parameters (e.g. activity) in order for PLANET Onco Dose to estimate the radiation doses that the tissues received as a result of the administration.
PLANET Onco Dose should only be used for the retrospective determination of dose and not for the case where there is a need for retreatment using Y90 microspheres.

[1] Bolch WE et al. MIRD pamphlet no. 17: the dosimetry of nonuniform activity distributions-Radionuclide S values at the voxel level. *J Nucl Med, 1999, 40:11S-36S*

7. Technological Characteristics:

The table below compares the technological characteristics and the features of PLANET Onco Dose and its predicate Velocity K173636.

PLANET Onco Dose (This submission)	Velocity K173636 (Predicate)
Indications for Use / Intended Use	
PLANET Onco Dose is a standalone software intended to be used with PET or SPECT hybrid imaging systems in order to manage, process, display and analyze nuclear medicine and other digital medical image series, to assist in medical diagnosis, to assist in treatment analysis and in therapy response assessment, to assist in the contouring of region of interest for radiotherapy. PLANET Onco Dose is dedicated to be used by qualified medical professionals in Molecular Imaging, and/or Medical Oncology.	Velocity is a software package that provides the physicians a means for comparison of medical data including imaging data that is DICOM compliant. It allows the display, annotation, volume operation, volume rendering, registration and fusion of medical images as an aid during use by diagnostic radiology, oncology, radiation therapy planning and other medical specialties. Velocity is not intended for mammography.
Device Type	
Standalone software	Standalone software
Users	
Qualified medical professionals in Molecular Imaging, and/or Medical Oncology	Physicians
Cybersecurity	

PLANET Onco Dose (This submission)	Velocity K173636 (Predicate)
Limits software access to trusted users only	Limits software access to trusted users only
Workflow	
Oncology workflow automation	Oncology workflow automation
Receive, store and retrieve digital DICOM medical images from a variety of sources and modalities PET/SPECT/CT/MRI	Receive, store and retrieve digital DICOM medical images from a variety of sources and modalities PET/SPECT/CT/MRI
Digital medical images patient's structured database	Organize data into a logical overview of a patient's imaging history
Image and registered image data export as DICOM series	Image and registered image data export as DICOM series
Structure Import, Save & Export as DICOM RT Object	Structure Import, Save & Export as DICOM RT Object
Dose data Import, Save & Export as DICOM RT Object	Dose data Import, Save & Export as DICOM RT Object
Reports can be exported as DICOM files	Reports can be exported as print sessions
Image Management Tools	
Support of 4D series	Support of 4D series with breathing cine mode
Advanced visualization and navigation features	Advanced visualization and navigation features
Management of multi-time point image series	Management of multi-time point image series
Manual registration methods including landmarks	Manual registration method
Automatic rigid image registration and fusion of medical series from multiple modalities	Automatic rigid image registration and fusion of medical series from multiple modalities
Automatic deformable image registration and fusion of medical images from multiple modalities	Automatic deformable image registration and fusion of medical images from multiple modalities
Combines images from different modalities for enhanced volume definition	Combines images from different modalities for enhanced volume definition
Visualization Tools	
General image viewer with view layout selection and toolbars	General image viewer with view layout selection and toolbars
2D visualization (Multi-planar)	2D visualization (Multi-planar)
3D volume rendering	3D volume rendering
Image fusion Anatomical and functional series	Image fusion Anatomical and functional series
Image analysis tools	Image analysis tools
General Contouring Features	
Multi-modality manual contouring tools	Multi-modality manual contouring tools
Contour transformation tools	Contour transformation tools
Semi-automatic advanced contouring tools	Contouring with automated scripting
Automated structure of interest segmentation tools	Atlas auto-segmentation
Propagates contours from one time point to another	Propagates contours from one time point to another
Contour transformation (interpolation, margining) between modalities	-
Functional Segmentation Tools	-

PLANET Onco Dose (This submission)	Velocity K173636 (Predicate)
Assessment Aid and Patient Follow-up Tools	
Visualization and analytical monitoring of disease progression or response to treatment or therapy using multiexam comparison and correlation	Visualization and analytical monitoring of disease progression or response to treatment or therapy using multiexam comparison and correlation
Quantification of metabolic activity and volume measurement of segmented tumors on PET modality	Volume operations Biological effective dose (BED) scaling
Measure Standard Uptake Value - SUV	Measure Standard Uptake Value - SUV
Advanced Tumor SUV Statistics	-
Patient's follow up analysis with volumetric graphs	Patient's follow up analysis with volumetric graphs
Allows generation of RECIST 1.1 & PERCIST 1.0 format reports.	-
Dose Distribution Import and Estimation Tools	
The dose distribution can be imported from any system such as radiation therapy planning systems using DICOM RT Dose format	The dose distribution can be imported from any system such as radiation therapy planning systems using DICOM RT Dose format
Intended for post-treatment absorbed dose calculation and evaluation Compatible with Y90 PET and SPECT image types	Intended for post-treatment absorbed dose calculation and evaluation Compatible with Y90 PET and SPECT image types
Use the Local Deposition Model for dose calculation	Use the Local Deposition Model for dose calculation
Use the Voxel S Value approach based on the schema in MIRD Pamphlet 17 ([1])	-
Dosimetry Analysis Tools	
Display of the dose distribution in patient tissues	Display of the dose distribution in patient tissues
Dose Volume Histogram statistics display	Dose Volume Histogram statistics display
Table of dose to organs	Table of dose to organs
Simultaneous display of two dose distributions and comparison tools	-
Addition of multiple treatment stages: internal dosimetry and/or external beam radiotherapy	Addition of multiple treatment stages: internal dosimetry and/or external beam radiotherapy
Operating System	
Linux operating system	Microsoft Windows and Apple macOS operating systems

8. Performance Testing – Bench:

PLANET Onco Dose was designed and documented in accordance with the recommandations of FDA “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” for software devices identified as Major Level of Concern.

PLANET Onco Dose was submitted to performance, functional and algorithmic testing, risk management assessment and validation activities under clinically representative conditions.
The results of performance, functional and algorithmic testing, risk management assessment and validation activities under clinically representative conditions demonstrate the safety and effectiveness of PLANET Onco Dose.

PLANET Onco Dose meets the requirements of the device, its user needs and intended use, which are demonstrated to be substantially equivalent to those of the predicate device.

9. Conclusions

The substantial equivalence discussion sustains the claim that PLANET Onco Dose intended use, clinical and technical (principles of operation, functionalities and critical performances) characteristics are the same as for the predicate device Velocity legally marketed in the U.S. (K173636).
The differences on some functional features do not significantly affect, or may not significantly affect, safety or effectiveness.

The results of verification and validation activities demonstrate the safety and effectiveness of PLANET Onco Dose.
PLANET Onco Dose meets the requirements of the device, its user needs and intended use, which are demonstrated to be substantially equivalent to those of the predicate device.

In summary, DOSIsoft therefore considers that, in its opinion, PLANET Onco Dose is substantially equivalent to and is at least as safe and effective as the predicate device.