March 14, 2025

DOSIsoft SA
Khalil Ahmed
Quality and Regulatory Affairs Responsible
45/47 Avenue Carnot
Cachan, 94230
France

Re: K241765
Trade/Device Name: PLANET Onco Dose (3.2)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 12, 2025
Received: February 12, 2025

Dear Khalil Ahmed:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JULIE SULLIVAN -S

Julie Sullivan, Ph.D.
Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241765

Device Name
PLANET Onco Dose (3.2)

Indications for Use *(Describe)*
PLANET Onco Dose is a standalone software intended to manage, process, display and analyze anatomical and functional images. It provides tools and functionalities to assist in medical diagnosis and therapy response assessment, to assist in the contouring of regions of interest, and to assist in internal dosimetry computation for radionuclide based therapies. The modalities of these medical imaging systems include CT, MRI, SPECT, PET, XA, planar scintigraphy, RT Struct and RT Dose as supported by ACR/NEMA DICOM 3 standard format.

PLANET Onco Dose is intended for retrospective determination of dose only and should not be used to deviate from approved radioactive products, product dosing and administration instructions.

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

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 (rigid and deformable), perform quantification for assessment and response evaluation of patients undergoing a course of oncology treatment.

PLANET Onco Dose allows import / export of results (contours and dosimetries) to / from any DICOM compliant system (e.g. Treatment Planning Systems, PACS).

PLANET Onco Dose allows to compute in 3D at the voxel scale the radiation doses received by tissues as a result of radionuclide administration. Dose can be computed with or without tissue density correction using two models depending on considered isotopes.

PLANET Onco Dose provided the User with the means to perform modeling of absorption and elimination kinetics of Radiopharmaceutical Therapy (RPT). Time-integrated activity and dose rate can be calculated from three kinds of clinical setups involving full 3D image acquisitions, hybrid 2D/3D image acquisitions and single time point approaches.

PLANET Onco Dose supports isotopes with beta and gamma contributions.
PLANET Onco Dose provides tools for dosimetry comparison for sequential treatments and for dosimetry summation.

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.

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

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Premarket Notification 510(k) Summary

[as required by 21 CFR 807.92]

510(k) Summary

1. Date the Summary was prepared: 2025-03-12

2. Contact Details

- Applicant Name: DOSIsoft SA
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- Correspondent Contact Telephone: +33 1 41 24 26 26
- Correspondent Contact: Mr. Ahmad KHALIL
- Correspondent Contact Email: regulatory@dosisoft.fr

3. Device Name

- Device Trade Name: PLANET Onco Dose (3.2)
- Common Name: Medical image management and processing system
- Classification Name: System, Image Processing, Radiological
- Regulation Number: 892.2050
- Product Code: LLZ

4. Legally Marketed Predicate Devices

- Primary Predicate # K182966

  Predicate Trade Name: PLANET Onco, PLANET Dose, PLANET Onco Dose (Version 3.1)

  Product Code: LLZ
- Secondary Predicate # K220630

  Predicate Trade Name: Torch™ Software

  Product Code: LLZ

Executive Summary

5. Device Description Summary

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

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

- PLANET – Core System: reviewing, fusion and registration of multi-modal anatomical (computed tomography (CT), magnetic resonance imaging (MRI), X-ray angiography (XA)) and functional (positron emission tomography (PET), single photon emission computed tomography (SPECT), planar scintigraphy) series;
- PLANET Onco – Oncology Module: contouring of region of interest, tumor segmentation, quantification, therapy response assessment;
- PLANET Dose – Dosimetry Module: pharmacokinetics modeling and internal dosimetry computation for locally regulatory approved pharmaceuticals.

6. Intended Use/Indications for Use

PLANET Onco Dose is a standalone software intended to manage, process, display and analyze anatomical and functional images. It provides tools and functionalities to assist in medical diagnosis and therapy response assessment, to assist in the contouring of regions of interest, and to assist in internal dosimetry computation for radionuclide based therapies. The modalities of these medical imaging systems include CT, MRI, SPECT, PET, XA, planar scintigraphy, RT Struct and RT Dose as supported by ACR/NEMA DICOM 3 standard format.

PLANET Onco Dose is intended for retrospective determination of dose only and should not be used to deviate from approved radioactive products, product dosing and administration instructions.

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

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 (rigid and deformable), perform quantification for assessment and response evaluation of patients undergoing a course of oncology treatment.

PLANET Onco Dose allows import / export of results (contours and dosimetries) to / from any DICOM compliant system (e.g. Treatment Planning Systems, PACS).

PLANET Onco Dose allows to compute in 3D at the voxel scale the radiation doses received by tissues as a result of radionuclide administration. Dose can be computed with or without tissue density correction using two models depending on considered isotopes.

PLANET Onco Dose provided the User with the means to perform modeling of absorption and elimination kinetics of Radiopharmaceutical Therapy (RPT). Time-integrated activity and dose rate can be calculated from three kinds of clinical setups involving full 3D image acquisitions, hybrid 2D/3D image acquisitions and single time point approaches.

PLANET Onco Dose supports isotopes with beta and gamma contributions.
PLANET Onco Dose provides tools for dosimetry comparison for sequential treatments and for dosimetry summation.

7. Indication for Use Comparison

PLANET Onco Dose Edition 3 Version 3.2 represents substantial equivalence to:

- DOSIsoft former version 3.1, trade name “PLANET Onco Dose” (K182966), and
- “Voximetry Torch™” (K220630) legally marketed devices in the U.S.

PLANET Onco Dose Version 3.2, Version 3.1 and Torch™ are standalone software for use in absorbed dose estimation of FDA approved radiopharmaceuticals.

All three devices are software devices designed to be used by medical physicists or physicians in a medical facility and do not involve any patient contact.

Compared to PLANET Onco Dose Version 3.1, PLANET Onco Dose Version 3.2 provides additional features dedicated to radiopharmaceutical therapy dosimetry that are also provided by Torch™.

8. Technological Comparison

PLANET Onco Dose and Torch™ share common technological characteristics such as:

- Support of multi-modality images: CT, SPECT, PET;
- Image registration;
- Management of volumes of interest;
- Importation of volumes of interest (DICOM RT-Structure format);
- Exportation of dose maps (DICOM RT-Dose format).

PLANET Onco Dose and Torch™ support FDA approved isotopes with beta and gamma emissions.

In the Version 3.2 of PLANET Onco Dose, the partial volume effect correction feature has been improved to enhance precision in quantitative analysis.

The main technological difference between PLANET Onco Dose version 3.2 and Torch™ is the dose computation algorithm that is used. PLANET Onco Dose uses two algorithms (voxel S Value dose kernel convolution and local energy deposition) while Torch™ uses Monte Carlo method.
Dose computation algorithms available in PLANET Onco Dose were compared with Monte Carlo method and the results showed consistency between evaluated methods.

All three devices allow the creation, transformation, and modification of contours / regions of interest to define objects in medical image volume to support treatment calculation and evaluation. Unlike PLANET Onco Dose, Torch™ does not provide segmentation tools.

Cybersecurity measures have been reinforced in PLANET Onco Dose Version 3.2 compared to its previous Version 3.1.

9. Non-Clinical and/or Clinical Tests Summary

PLANET Onco Dose Edition 3 Version 3.2 was designed and documented in accordance with the recommendations of FDA "Guidance for the Content of Premarket Submissions for Device Software Functions".

PLANET Onco Dose was submitted to performance, functional and algorithmic testing, risk management assessment, including cybersecurity 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.

As part of verification, the demonstration of performance covers each workflow supported by PLANET Onco Dose Edition 3 Version 3.2:

- Standard SIRT workflow;
- Full SPECT/CT pharmacokinetics for MRT;
- 2D/3D hybrid pharmacokinetics for MRT;
- Single time point pharmacokinetics for MRT.

The substantial equivalence discussion sustains the claim that PLANET Onco Dose shares the same intended use, clinical and technical characteristics as the predicates PLANET and Torch™ legally marketed in the U.S.

PLANET Onco Dose Edition 3 Version 3.2 is comparable with previous release Version 3.1 for its image processing & oncology functionalities and with Torch™ for its dosimetry computation and analysis functionalities. Torch™ implements a Monte Carlo dose calculation, while PLANET Onco Dose Edition 3 Version 3.2 implements a Voxel S Value dose kernel convolution algorithm, giving substantially equivalent performance, therefore not affecting safety and effectiveness. Both devices compute doses at voxel level for FDA approved radionuclides.
The differences on some other functional features do not significantly affect, or may not significantly affect, safety or effectiveness.

The critical evaluation of the relevant scientific literature confirms that the choices made for the TRT dosimetry computation methods implemented within PLANET Onco Dose are those recommended by the scientist international community.
Furthermore, the performance obtained by the demonstration of performances lead to clearly define the area of application of the various internal dosimetry methods of the product PLANET Onco Dose for the TRT / MRT over the course of the therapy.

In the context of cybersecurity, the device is considered sufficiently safe for its intended use as risks discovered by the penetration testing, have been mitigated as far as possible. The results of verification and validation activities demonstrate the safety and effectiveness of PLANET Onco Dose.

10 Conclusion

The substantial equivalence discussion sustains the claim that PLANET Onco Dose (3.2) shares the same intended use, clinical and technical characteristics as the predicates PLANET Onco Dose (Version 3.1) and Torch™, legally marketed in the U.S. (K182966 and K220630).

In conclusion, PLANET Onco Dose (3.2) aligns with the device requirements, user needs, and intended use, showcasing substantial equivalence to the predicate devices. Differences in certain features are assessed to have either negligible impact or no significant effect on safety and effectiveness. Thus, DOSIsoft asserts that PLANET Onco Dose (3.2) is substantially equivalent to its predicate devices.