

PRESS RELEASE

DOSIsoft announces new FDA 510(k) clearance for PLANET® Onco Dose

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DOSIsoft, SA, a leading provider of patient-specific imaging and dosimetry software solutions for radiation oncology and nuclear medicine, is proud to announce its latest product release, PLANET® Onco Dose version 3.2 received FDA 510(k) Clearance on March 14, 2025, from the US Food and Drug Administration, following its EU MDR CE Mark certification.

The novel PLANET® platform is designed to incorporate a **multi-radionuclide** approach, implement **multi-workflow** solutions, and support **multi-therapy** applications for both **SIRT** (Selective Internal Radiation Therapy) and **MRT** (Molecular Radiation Therapy) while ensuring compliance with U.S. standards.

Extended to ¹⁷⁷Lu -¹³¹I Targeted Radionuclide-based Therapies (TRT)

Although a previous version of PLANET® Onco Dose was FDA 510(k)-cleared for use with **⁹⁰Y resin and glass microspheres**, this new clearance for the latest software version expands clinical capabilities to include dose computation for **¹³¹Iodine** and **¹⁷⁷Lutetium**. It also offers the flexibility to integrate **additional beta- and gamma-emitting isotopes**, adapting to evolving clinical needs.

Introducing new Multiple & Single-Time Point Workflows for Systemic Therapy

Already clinically marketed in the US for oncology features and ⁹⁰Y-SIRT post-treatment dosimetry, the new version of PLANET® Onco Dose enhances **MRT** dosimetry (¹⁷⁷Lu and ¹³¹I) workflows. It implements full 3D and 2D/3D hybrid methods for **multi-time point workflows**, as well as the newly introduced **single-time point workflow** to reduce workload, enhance patient comfort, and streamline clinical processes. In this context, the user can benefit from two approaches to perform dosimetry from a single-time point image acquisition: leveraging pharmacokinetics from the **prior cycle** or applying the **population-based/Hänscheid** approach.

Expanded to Support a Broad Range of Treatments

The software can support multiple therapies including **¹⁷⁷Lu-PSMA** (prostate-specific membrane antigen) therapy, **¹⁷⁷Lu-PRRT** (peptide receptor radionuclide therapy), **⁹⁰Y radioembolization**, **¹³¹I therapies**, enabling highly personalized treatment for each patient.

Additionally, PLANET® Onco Dose version 3.2 operates on a new, long-term supported operating system with enhanced cybersecurity, ensuring compatibility with the latest workstation generations. Validated against thorough Monte-Carlo simulations, this new release also benefits from GPU acceleration to deliver significantly improved performance.

*"PLANET® Onco Dose is now available for clinical implementation in the U.S., supporting multiple therapies, radionuclides, and workflows. This achievement is the result of a collective effort by DOSIsoft to meet all U.S. FDA requirements" highlights Jean-Elie Kafrouni, CEO at DOSIsoft Inc., "This new version positions **PLANET® Onco Dose ahead of the competition**, offering clinicians **a comprehensive and adaptable solution for precision dosimetry**. We look forward to seeing US patients benefit from this safe and effective device designed for Radiopharmaceutical Therapy (RPT)."*

To learn more about PLANET® Onco Dose, the patient-specific Theranostics solution, visit DOSIsoft at the SNMMI Annual Meeting (Booth #1503, June 21–25, 2025)

About PLANET®

PLANET® Onco Dose Edition 3 is developed by DOSIsoft SA in France. It is a Class IIb CE-marked medical device under MDR (EU) 2017/745 and is US FDA 510(k) cleared. Availability of the product or specific features may vary by country and regulatory approval status.

About DOSIsoft

Founded in 2002, DOSIsoft stands as market leader specialized in dosimetry software in Radiation Oncology and Nuclear Medicine to improve cancer patient safety & treatment quality. We provide the most competitive patient-specific quality assurance and medical imaging solutions in over 600 hospital centers in 60 countries. Spin-off between Gustave Roussy and Curie Institute in France, DOSIsoft constantly innovates in partnership with the major cancer institutes and research centers in the world. www.dosisoft.com

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