



September 4, 2025

Mvision AI Oy
Kalpana Jha
VP of Regulatory and Market Strategy
Paciuksenkatu 29
6th Floor
Helsinki, 00270
Finland

Re: K250064

Trade/Device Name: Dose+
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: January 10, 2025
Received: August 6, 2025

Dear Kalpana Jha:

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,



Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
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

Indications for Use

Submission Number (if known)

K250064

Device Name

Dose+ (1.0)

Indications for Use (Describe)

Dose+ is a software-only medical device intended for use by qualified, trained radiation therapy professionals (including but not limited to medical physicists, radiation oncologists, and medical dosimetrists). The device is intended for male patients with localized prostate cancer or prostate cancer with pelvic lymph node involvement who are undergoing external beam radiation therapy treatment. The software uses machine learning-based algorithms to automatically produce 3D dose distributions from patient-specific anatomical geometry and target dose prescription.

The predicted dose distribution output is required to be transferred to a radiotherapy treatment planning system (TPS) or reviewed by any DICOM-RT compliant software prior to further use in clinical workflows. Dose+ is intended to provide additional information during the treatment planning process facilitating the creation and review of a treatment plan.

Dose+ is not intended to be used for disease diagnosis and treatment decision purposes in clinical workflows

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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510(k) Summary

The following information is provided as required by 21 CFR 807.92

Date Prepared: January 10, 2025

Submitter's Information

Company Name and Address	MVision AI Oy Paciuksenkatu 29, 6th floor 00270 Helsinki, Finland Tel: +358 040 5489229 Website: www.mvision.ai
Contact Person	Kalpana Jha VP of Regulatory and Market Strategy kalpana.jha@mvision.ai Tel: +358 44 9214 354
Establishment Registration Number	3022745617

Subject Device

Device Trade Name	Dose+
Device Classification Name	System, Planning, Radiation Therapy Treatment
Product Code	MUJ
Regulation	Medical charged-particle radiation therapy system (21 CFR 892.5050)
Device Class	Class II
Review Panel	Radiology

Predicate Device

Device Name	Oncospace
510(k) Number	K222803
Manufacturer	Oncospace, Inc.

This predicate has not been subject to a design-related recall.

Device Description

Dose+ is a software-only medical device that assists radiation oncologists, medical dosimetrists and medical physicists during external beam radiotherapy treatment planning. The software utilizes pre-trained machine learning models that are not modifiable or editable by the end-user. The product provides information during the radiotherapy plan creation but does not replace a treatment planning system (TPS).

The central value proposition of Dose+ is to provide personalized organ-at-risk (OAR) dose optimization goals based on individual patient anatomy, rather than relying solely on population-based protocol templates. The software analyzes patient-specific anatomical geometry to determine achievable dose levels for each OAR relative to target volumes. This helps to ensure:

- Initial optimization objectives are more achievable, reducing the number of iterations needed during plan optimization
- Opportunities for further OAR dose reduction are not missed when standard fixed templates suggest a higher dose
- Inappropriately aggressive goals for one OAR do not compromise target coverage or dose reduction to other OARs

The device operates in two deployment modes:

- Cloud-based service with secure HTTPS data transfer
- Local installation in healthcare provider's IT network

Key features include:

- Automated dose prediction using locked machine learning models
- Generation of DICOM RT Dose objects
- Integration with existing treatment planning workflows
- Support for multiple fractionation schemes
- Compatibility with major treatment planning systems

The first release includes two models for male pelvis patients:

- “Prostate” model: For localized prostate treatments
- “PelvisLN” model: Designed for cancers involving lymph nodes

Intended Use / Indications for Use

Dose+ is a software-only medical device intended for use by qualified, trained radiation therapy professionals (including but not limited to medical physicists, radiation oncologists, and medical dosimetrists). The device is intended for male patients with localized prostate cancer or prostate cancer with pelvic lymph node involvement who are undergoing external beam radiation therapy treatment. The software uses machine learning-based algorithms to automatically produce 3D dose distributions from patient-specific anatomical geometry and target dose prescription.

The predicted dose distribution output is required to be transferred to a radiotherapy treatment planning system (TPS) or reviewed by any DICOM-RT compliant software prior to further use in clinical workflows. Dose+ is intended to provide additional information during the treatment planning process facilitating the creation and review of a treatment plan.

Dose+ is not intended to be used for disease diagnosis and treatment decision purposes in clinical workflows.

Comparison of Technological Characteristics

The following table summarizes the similarities and differences between Dose+ and the predicate device that support the claim of substantial equivalence.

Device Characteristic	Subject Device (Dose+)	Predicate Device (Oncospace, K222803)	Comparison
Product Code	MUJ	MUJ	Same
Device Classification	System, Planning, Radiation Therapy Treatment	System, Planning, Radiation Therapy Treatment	Same
Intended Use / Indication for Use	<p>Dose+ is a software-only medical device intended for use by qualified, trained radiation therapy professionals (including but not limited to medical physicists, radiation oncologists, and medical dosimetrists). The device is intended for male patients with localized prostate cancer or prostate cancer with pelvic lymph node involvement who are undergoing external beam radiation therapy treatment. The software uses machine learning-based algorithms to automatically produce 3D dose distributions from patient-specific anatomical geometry and target dose prescription.</p> <p>The predicted dose distribution output is required to be transferred to a radiotherapy treatment planning system (TPS) or reviewed by any DICOM-RT compliant software prior to further use in clinical workflows. Dose+ is intended to provide additional information during the treatment planning process facilitating the creation and review of a treatment plan.</p>	<p>Oncospace is used to configure and review radiotherapy treatment plans for a patient with malignant or benign disease in the prostate, head, and neck regions. It allows for the set up of radiotherapy treatment protocols, association of a potential treatment plan with the protocol(s), submission of a dose prescription and achievable dosimetric goals to a treatment planning system, and review of the treatment plan. It is intended for use by qualified, trained radiation therapy professionals (such as medical physicists, oncologists, and dosimetrists). This device is for prescription use by order of a physician.</p>	Both devices provide dosimetric guidance for external beam radiotherapy treatment planning.

Device Characteristic	Subject Device (Dose+)	Predicate Device (Oncospace, K222803)	Comparison
	Dose+ is not intended to be used for disease diagnosis and treatment decision purposes in clinical workflows.		
Typical Users	Radiation therapy professionals, including medical physicists, oncologists, and dosimetrists	Radiation therapy professionals, including medical physicists, oncologists, and dosimetrists	Same
Patient Population	Patients with malignant or benign disease in the prostate undergoing external beam radiation therapy	Patients with malignant or benign disease in the prostate, head, and neck regions undergoing external beam radiation therapy	The subject device is not indicated for head and neck treatments
Platform	Client-Server Architecture (Clinic-provided client machines or cloud servers controlled by the manufacturer)	Client-Server Architecture (Clinic-provided client machines or cloud Windows servers controlled by the manufacturer)	Same architecture; Different only in the operating system of the cloud servers
Operating System (OS)	Windows Client, Linux Server	Windows (Client and Server)	Different only in the OS of the cloud servers
DICOM-RT Compliant	Yes	Yes	Same
Full Treatment Planning System	No	No	Same
Connected to or Controlling of Radiation Delivery Devices	No	No	Same
Input Data	A patient's CT images, RT Structure sets and target dose prescription in ROI names	A patient's CT images, RT Structure sets and target dose in treatment protocols or user specified	Same patient-specific data. Input explicitly provided to Dose+, while the predicate device requires user input or the creation of protocol templates.
Processing and Device Output	Processes input using locked machine learning (ML) models trained on patient-specific anatomical geometry to generate the predicted 3D dose distribution	Processes treatment plan data using locked machine learning (ML) models trained on patient-specific anatomical geometry to predict achievable dosimetric goals/ objectives for OARs	Same processing fundamentals but different ML models (complete 3D dose prediction vs. dosimetric objectives prediction for OARs).

Device Characteristic	Subject Device (Dose+)	Predicate Device (Oncospace, K222803)	Comparison
Output Format	Exports DICOM RT Dose objects with complete 3D dose distribution that may be reviewed using a third-party DICOM-RT compliant software or that may be directly transferred to a radiotherapy treatment planning system (TPS) for review prior to further use in clinical workflows	Exports dosimetric goals/objectives in different specific formats for review in a treatment planning system (TPS) prior to further use in clinical workflows	Different output formats but both devices provide dosimetric information to assist with plan optimization during treatment planning.
Plan Review Functionality	Does not include treatment plan review features.	Contains integrated features and GUI for treatment plan review, including DVH visualization	Different. Dose+ relies on existing third party TPS review functionality.

Performance Data

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

In addition to software verification testing, the following performance verification and validation data was submitted in support of substantial equivalence determination.

Device Dataset were partitioned into three non-overlapping sets (in terms of patients): Model Development (with internal splits for training, validation, and testing during the model development), Performance Verification (independent, in-house assessment of final models), and Clinical Validation (U.S.-focused validation in US clinics).

Samples in all the datasets are collected from distinct and individual patients, hence the number of cases are the same as the number of patients.

Both Model Development Dataset and Performance Verification Dataset included multiple CT scanner models and manufacturers (including GE Medical Systems, Philips and Canon Medical Systems/Toshiba). In addition, the validation datasets from the US included demographic diversity with balanced ethnic representation, particularly including Caucasian and African American populations. This demographic and technological diversity in the dataset helped to ensure Dose+ models perform consistently across diverse patient populations and various imaging equipment configurations commonly encountered in clinical practice.

Performance Verification

Performance verification was conducted using an independent dataset to demonstrate non-inferiority in OAR mean dose predictions and target coverage against manual planning. This test dataset includes cases from multiple US institutions to ensure representation of the US population and medical practice.

The Performance Verification Dataset is completely separate and independent from the Model Development Dataset, with NO overlapping patients between these datasets. Dataset also aims to have minimal overlap of sources/clinics between the model development and performance verification dataset. This strict separation ensures unbiased evaluation of model performance. Verification Dataset

- Prostate Model: Verification Dataset is 100% US dataset, and includes (25/25) cases from 7 U.S. institutions across 6 US states
- PelvisLN Model: Verification Dataset is 96.3% US dataset, and includes (26/27) from 6 institutions from 6 US states

Key verification metrics included:

- OAR Mean Dose Difference (acceptance criterion: ≤ 10 Gy)
- Target coverage metrics (homogeneity and conformity indices)

Results demonstrated that both prostate and pelvisLN models of Dose+ met all predefined acceptance criteria for OAR mean doses and target coverage metrics, showing strong correlation between predicted and ground truth dose distributions.

Performance Validation

Clinical validation was conducted at 4 geographically diverse US institutions across 3 states with qualified radiation therapy professionals on 100% US dataset. The device was validated on patients aged 60 years and older. Demographic representativeness in the validation dataset closely matches the US national median age of 67 years at prostate cancer diagnosis reported in the [NCI SEER database](#) (mean age 65.0 ± 6.7 years for the prostate model and 66.9 ± 7.7 years for the pelvisLN model).

The validation study tested:

- Non-inferiority in plan quality (both OAR sparing and target coverage) compared to conventional planning
- Reduction in optimization iterations when using Dose+ compared to conventional planning
- User acceptance and workflow integration

Study design:

- Prospective patient enrollment
- Within-subject comparison (with/without Dose+ assistance)
- Independent validators (ABR-certified medical physicists)
- Sample size determined through statistical power analysis

Success criteria:

- Statistically significant reduction in optimization iterations ($\geq 20\%$ mean reduction)
- Non-inferior OAR mean doses (≤ 10 Gy difference)

- Non-inferior target coverage (no statistically significant differences)
- Positive user acceptance from validators
- No identified safety issues

The study results demonstrated that both prostate and pelvisLN models of Dose+ met all predetermined success criteria. Importantly, no safety hazards were identified during validation testing. The majority of validators indicated willingness to use the system clinically and reported potential time savings in treatment planning.

Conclusion

The subject device Dose+ has the same intended use and similar technological characteristics as the predicate device. The differences in technological characteristics do not raise new questions of safety or effectiveness as demonstrated through software system design, risk management and testing. Software system verification testing, non-clinical performance verification, and clinical performance validation confirm that Dose+ meets design specifications and user needs. Moreover, like the predicate device, Dose+ produces results that are equivalent to conventional treatment planning for OAR sparing and target coverage while reducing optimization iterations. The conclusions drawn from non-clinical and clinical testing demonstrate that Dose+ is as safe, as effective, and performs as well as the legally marketed predicate device for the stated indications for use.