November 20, 2025

COSYLAB JSC, Control System Laboratory
Matija Rupnik
Regulatory Affairs Manager
Gerbiceva ulica 64
Ljubljana, 1000
Slovenia

Re: K250963
Trade/Device Name: PlanOne 1
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: October 22, 2025
Received: October 23, 2025

Dear Matija Rupnik:

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 Device
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.

Submission Number *(if known)*

K250963

Device Name

PlanOne 1

Indications for Use *(Describe)*

The PlanOne is a software system used to plan radiotherapy treatments for patients with malignant or benign diseases. PlanOne is used to plan external beam irradiation with photon and proton beams. The intended users of PlanOne shall be clinically qualified radiation therapy staff trained in using the system.

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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510(k) Summary

21 CFR § 807.92

1. Contact Details

Applicant

COSYLAB JSC, Control System Laboratory

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Contact

Mr. Matija Rupnik

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Prepared on: 2025-11-19

2. Device Name

Device Trade Name

PlanOne 1

Common Name

Medical charged-particle radiation therapy system

Classification Name

System, Planning, Radiation Therapy Treatment

Regulation Number

892.5050

Product Code(s)

MUJ

3. Legally Marketed Predicate Devices

Predicate #

K230557

Predicate Trade Name

Eclipse Treatment Planning System (v18.0)

Product Code

MUJ

4. Device Description Summary

The Cosylab Treatment Planning System (PlanOne) is responsible for creating machine instructions (treatment plans) for radiotherapy. It's a complex piece of software, integrating detailed physics (dose calculation), mathematics (plan optimization) and graphical (contouring) algorithms.

The PlanOne has to import 3D image datasets of patient anatomy, usually CT images. In the first stage of the planning, the tumor and critical structures have to be identified by the user. The process is called contouring.

In the second stage, the 3D image and the contours are taken along with prescription input to calculate a treatment plan. The treatment plan includes machine instructions on how to deliver radiation.

To produce an appropriate treatment plan, the PlanOne computes the expected dose distribution in the patient's anatomy, taking into account relative electron density and particle stopping material properties at specific voxels (pixels). The PlanOne also helps to navigate beam placement based on avoiding critical structures that are more sensitive to radiation in an effort to reduce collateral damage from the therapy. The PlanOne may optimize beam shape and intensity to meet the user set objectives. This may include automated, complex programming for multi-leaf collimator (MLC) leaf sequencing to shape the beam around critical structures during dose delivery. In particle therapy instead of shaping MLC, the PlanOne determines the appropriate spot placement and weight in each beam direction.

5. Intended Use/Indications for Use

The PlanOne is a software system used to plan radiotherapy treatments for patients with malignant or benign diseases. PlanOne is used to plan external beam irradiation with photon and proton beams. The intended users of PlanOne shall be clinically qualified radiation therapy staff trained in using the system.

Indications for Use Comparison

The PlanOne device has similar indications for use as the predicate device, with exception that the PlanOne use is limited to plan external beam irradiation with photon and proton beams only. The difference is only in limited options of supported treatments in comparison to the predicate device, therefore the differences do not constitute a new intended use.

6. Technological Comparison

Both the predicate device Eclipse Treatment Planning System (v18.0) and the subject PlanOne 1 device are based on the same technological characteristics:

- They both provide software tools for planning the treatment of malignant or benign diseases with radiation.
- They are both software devices used by clinically qualified radiation therapy staff trained to design and simulate radiation therapy treatments.
- They are both capable of planning treatments for external beam irradiation with photon and proton beams.

The predicate device, Eclipse Treatment Planning System (v18.0), and the subject device, PlanOne 1, share the same fundamental technological purpose and operational role: both are software-based radiotherapy treatment planning systems used by qualified clinical staff to design, calculate, and evaluate external beam treatments using photon and proton modalities.

The Table 1 summarizes the elements of substantial equivalence and outlines the technological and functional differences between PlanOne 1 and the predicate device.

Overall, the differences identified between PlanOne 1 and the predicate device do not raise new questions of safety or effectiveness. The devices employ comparable technological characteristics, support the same clinical use, and demonstrate equivalent performance for the intended treatment planning functions.

Performance equivalence has been demonstrated through comprehensive non-clinical testing, summarized in Section 7 of this document.

Table 1: Summary of the Substantial Equivalence Comparison

Category	**Predicate Device: Eclipse v18.0**	**Subject Device: PlanOne 1**	**Comparison Statement**
Intended Use / Indications for Use	EBRT with photons, electrons, protons; brachytherapy	EBRT with photons and protons	Indications are equivalent except that PlanOne omits electrons and brachytherapy (see Footnote 1).
Beam Modalities Supported	Photons, electrons, protons; non-coplanar setups; MLCs; wedges; cones; Halcyon; Elekta machines	Photons and protons only; Varian TrueBeam platforms; standard MLCs; wedges; arcs	Core photon and proton features equivalent. Missing modalities do not change intended use (Footnote 2).
Treatment Planning Capabilities	3D, IMRT, VMAT, SRS, 4D, robust photon planning, Halcyon, brachytherapy	3D, IMRT, VMAT; no SRS, no 4D planning, no Halcyon, no brachytherapy	PlanOne provides core external photon & proton planning functionality; unsupported features are

Category	Predicate Device: Eclipse v18.0	Subject Device: PlanOne 1	Comparison Statement
			optional enhancements in predicate (Footnote 3).
Image & Structure Processing	CT/MR/PET import; deformable registration; atlas-based segmentation; 4D image tools	CT/MR/PET import; rigid registration; manual/semiautomatic segmentation	Predicate includes additional optional image-processing tools; PlanOne supports clinically essential contouring workflows (Footnote 4).
Dose Calculation Algorithms (Photon)	AAA, pencil beam, electron dose; compensators	CCC (collapsed cone); no electrons; no compensators	PlanOne uses clinically validated CCC algorithm (Footnote 5).
Photon Monte-Carlo	AcurosXB; plan and range uncertainty for photon plans	Not supported in PlanOne	Missing functions do not affect core intended use (Footnote 6).
Dose Calculation Algorithms (Proton)	Monte Carlo; robust optimization; multiple scattering techniques	Monte Carlo; robust optimization; scanning only	Equivalent for scanning-beam proton planning (Footnote 7).
Optimization Capabilities	Photon & proton MCO, beam-angle optimization, SRS tools, 3D conformal optimization	Photon & proton optimization; no MCO; no beam-angle optimizer; no 3D conformal optimization	Missing functions do not affect core intended use (Footnote 8).
Import/Export Connectivity	ARIA integration; ESAPI scripting; Varis DB; DICOM	DICOM-RT import/export; PlanOne scripting	PlanOne supports essential DICOM-RT interoperability (Footnote 9).
Evaluation Tools	DVH, isodose, 3D/BEV, biological models	DVH, isodose, 3D/BEV, biological models	Equivalent functionality.

Footnotes:

Footnote 1 – Indications for Use

- PlanOne excludes electron planning and brachytherapy.
- These are optional modalities in the predicate and do not represent a different intended use.
- Users remain identical (qualified radiation oncology staff).

Footnote 2 – Supported External Beams

- Details of unsupported features: electron beams, brachytherapy, Halcyon, Elekta MLCs, SRS cones.
- PlanOne supports all features needed for EBRT photon planning on TrueBeam systems as well as planning for proton pencil beam scanning.

Footnote 3 – Planning Capabilities

- PlanOne provides clinically essential tools for IMRT, VMAT, and 3D conformal.
- Missing features (SRS, 4D planning, Halcyon) relate to scenarios outside PlanOne's intended device scope.

Footnote 4 – Contouring & Image Processing

- Eclipse advanced tools include deformable registration and atlas-based segmentation.
- PlanOne offers manual and semiautomatic tools and fully supports DICOM-RT import/export.

Footnote 5 – Photon Dose Calculation

- PlanOne uses Collapsed Cone Convolution (CCC), validated against measurements and Monte Carlo.
- Differences between CCC and AAA/AcurosXB are described in IFU; accuracy meets clinical standards.

Footnote 6 – Photon Monte-Carlo

- For photon plans, the plan and range uncertainties are sufficiently included in the widely accepted concepts of PTV (planning target volume), ITV (irradiated target volume) and PRV (Planning Organ at Risk Volume), during the contouring process by the intended users.

Footnote 7 – Proton Dose Calculation

- PlanOne supports Monte Carlo-based scanning proton planning.
- Eclipse supports additional scattering techniques not relevant to PlanOne's scope.

Footnote 8 – Optimization

- Missing features (beam-angle optimization, multi-criteria optimization) do not impact safety or intended use.
- PlanOne supports robust optimization for proton beams.

Footnote 9 – Connectivity

- Eclipse proprietary interfaces (ARIA, Varis, ESAPI) are not included.
- PlanOne supports full DICOM-RT interoperability for clinical workflows.

PlanOne 1 has similar technological characteristics and features as the previously cleared predicate device, with the above listed differences, that do not adversely impact safety or effectiveness and therefore do not raise new questions of safety or efficacy.

7. Non-Clinical and/or Clinical Tests Summary

The subject device verification and validation were performed and the documentation was provided as recommended by the FDA's Guidance for Industry and Food and Drug Administration Staff: "Content of

Premarket Submissions for Device Software Functions". The Software Documentation Level determined for this device was "Enhanced Documentation".

The subject device conforms in whole or in part with the following standards:

- IEC 62304:2006+AMD 1:2015 - Medical device software - Software life cycle processes
- IEC 81001-5-1:2021 - Health software and health IT systems safety, effectiveness and security
- IEC 62366-1:2015+COR1:2016+A1:2020 - Medical devices – Part 1: Application of usability engineering to medical devices
- IEC 62083:2009 - Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems
- IEC 61217:2011 - Radiotherapy equipment - Coordinates, movements, and scales
- ISO 15223-1:2021 - Medical devices - Symbols to be used with information to be supplied by the manufacturer
- ISO 20417:2021 - Information supplied by the manufacturer of medical devices
- ISO 14971:2019 - Medical devices - Application of risk management to medical devices
- ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes

The following verification and validation activities have been performed in accordance with FDA guidance recommendations to confirm the device design met all specifications, user needs, and was acceptable to qualified clinical users:

- Unit verification (verification activities, including code reviews, performed at the software unit level to confirm correct implementation of design specifications).
- Requirements verification (verification of the software system and all associated components and functionalities – including integration verification – as documented in component-level and system-level testing documentation).
- Regression testing (verification that software updates or changes, as identified through change impact analysis, do not adversely affect existing functionality).
- Penetration testing (evaluation of the subject device's security controls to identify and assess potential vulnerabilities).
- Usability validation (evaluation demonstrating that intended users can safely and effectively interact with the subject device under expected conditions of use).
- Clinical validation (evaluation demonstrating that the software's outputs are clinically accurate, reliable, and appropriate for the intended use population and clinical environment). Please note that this validation is not related to clinical trials but to the evaluation of the subject device results in a clinical environment, i.e. beam model validation, dose-calculation accuracy testing, inverse-planning verification, and patient-case evaluation.
- PlanOne performance validation (confirmation through objective evidence that the software system, when integrated and used as intended, consistently fulfills user needs, intended uses, and regulatory requirements under expected operating conditions).

The non-clinical verification, validation, and performance testing activities were comprehensively planned, executed, and reviewed to ensure that the device design meets user needs, intended use, and specified performance requirements. The validation further demonstrates the system's accuracy, deliverability, and clinical suitability in accordance with established and internationally accepted standards. PlanOne 1 successfully met the acceptance criteria for all tests performed, and the resulting evidence demonstrates

conformity with applicable requirements and specifications. Based on the results of this evaluation, PlanOne 1 is concluded to be substantially equivalent to the predicate device.

The results of non-clinical performance testing are presented in the table below.

Table 22: Non-Clinical Performance Testing Summary

Test Category	Description of Test	Acceptance Criteria	Summary of Results
Beam Model Validation – Photons	Comparison of TPS-calculated PDDs, profiles, and output factors to measured commissioning data (6X, 10X, 15X; various field sizes; with and without flattening filter; EDW where applicable).	2%/2 mm gamma, ≥95% pass rate for PDD and profiles; Output factors validated.	All energies met criteria. Minor tail-region deviations for large fields consistent with CCC behavior; clinically insignificant.
Beam Model Validation – Protons	Validation of proton Monte Carlo engine against TOPAS/measurement.	Spot sigma ± 2%; R20 and R80 values ± 0.5 mm.	All proton validation cases met criteria. Range shifters also validated.
MLC & Jaw Modeling	Leaf transmission, interleaf leakage, tongue-and-groove, small-field behavior. Compared to measurements.	2%/2 mm gamma, ≥95% pass rate	Final model met all criteria.
Heterogeneity & Interface Testing	Lung, air, bone, soft-tissue interfaces; slab phantoms; compared against Monte Carlo.	3%/2 mm gamma ≥95% for dose in homogeneous and heterogeneous regions.	All tests met acceptance; expected differences vs AAA in low-density regions documented.
Dose Algorithm Accuracy	CCC photon calculations vs Eclipse/MC; Monte Carlo proton vs TOPAS.	Metrics within clinical tolerance; visual agreement of isodose and DVH.	Agreement demonstrated across all cases; known differences documented (lung, air cavities, penumbra in large fields).
Inverse Planning Accuracy (IMRT/VMAT)	TG-119/TG-244 IMRT and VMAT plans recalculated and compared.	3%/2 mm gamma ≥95%; clinical goals met.	All cases passed. PlanOne met all clinical goals and produced results comparable to predicate TPS.
Robust Proton DSS Optimization	Robust discrete scanning proton optimization validation under setup and range uncertainties.	Robust goals achieved; DVH and isodose review acceptable to expert planners.	All robust and non-robust plans met clinical acceptability criteria.

Patient Case Validation (Photons)	Nine anonymized clinical photon cases (lung, prostate, breast, H&N, spine). Eclipse/ArcCHECK comparison.	Clinical goals met; ≥95% gamma; deliverability confirmed.	All goals met; expected differences for air-cavity spine case documented.
Patient Case Validation (Protons)	Representative proton cases: prostate and liver. MC reference.	Robust targets/OARs meet constraints; DVH within tolerance.	All cases clinically acceptable; MC agreement demonstrated.
End-to-End Dose QA (ArcCHECK)	Delivery QA with ArcCHECK for subset of plans.	≥95% gamma at 3%/2 mm.	All delivered plans passed QA; example reports included.
Plan Deliverability Checks	Mechanical constraints: MLC carriage, gantry, couch, MU limits, SRS flags.	All deliverable plans must satisfy machine limits.	Identified non-deliverable SRS-like test plan; documented as unsupported.
DICOM-RT Interoperability	Import/export, round-trip, and conformance testing including CT, RTPLAN, RTDOSE, RTSTRUCT.	Correct import/export; geometric integrity maintained.	All tests passed; known bolus import difference noted for Eclipse.
System Functionality Tests	GUIs, scripting, optimization workflow, plan review tools.	Must meet software requirements.	All tests passed.
Stress and Boundary Condition Testing	Large plans, long arcs, high-MU IMRT, large structures, etc.	System must remain stable; algorithm must produce valid results.	System stability confirmed. Expected behavior for very large fields and extreme geometries documented.

No animal studies or clinical trial tests have been included in this pre-market submission.

8. Conclusion

The subject PlanOne 1 device is similar in intended use and functionality to the predicate device. PlanOne 1 has similar technological characteristics and features as the previously cleared predicate device, with some differences in supported features that do not adversely impact safety or effectiveness and do not raise new questions of safety or efficacy, as demonstrated through the system design and non-clinical performance testing.

Comprehensive non-clinical verification, validation, and performance testing were conducted to confirm that the device meets its design specifications, intended use, and user needs. These activities included software verification and validation, usability validation, cybersecurity testing, and extensive system-level performance testing of all photon and proton treatment-planning functions. The results demonstrate

conformance to applicable requirements and show that the device performs as intended across all evaluated use scenarios.

It is therefore concluded that the subject device PlanOne 1 is substantially equivalent to and considered to be safe and effective and perform at least as well as the predicate device Eclipse Treatment Planning System v18.0 (K230557).