September 12, 2025

Mevion Medical Systems, Inc.
Jason Brown
Director, Quality and Regulatory Affairs
300 Foster St.
Littleton, Massachusetts 01460

Re: K250986
Trade/Device Name: S250-FIT Proton Beam Radiation Therapy Device
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: LHN
Dated: August 15, 2025
Received: August 15, 2025

Dear Jason Brown:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250986

Device Name
S250-FIT Proton Beam Radiation Therapy Device

Indications for Use *(Describe)*
The MEVION S250-FIT Proton Beam Radiation Therapy Device is intended to deliver proton radiation treatment to patients with localized tumors or any other conditions susceptible to treatment by radiation. When the patient is in the fully seated position, the MEVION S250-FIT is indicated for treatment of patients with localized tumors and other conditions susceptible to treatment by radiation in the sites above the mid-chest or carina.

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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Traditional 510(k) Summary

Mevion Medical Systems Inc.

Mevion S250-FIT Proton Beam Radiation Therapy Device

I. Submitter

Mevion Medical Systems Inc.

300 Foster St

Littleton, MA 01460

USA

Contact:

Jason Brown

Jason.Brown@Mevion.com

510(k) Number: K250986

Date: September 10, 2025

II. Device

Device Trade Name: S250-FIT Proton Beam Radiation Therapy Device

Product Classification: Class II

Common Name: Medical charged-particle radiation therapy system

Classification Name: System, Radiation Therapy, Charged-Particle, Medical

Regulation Number: 892.5050

Product Code: LHN

III. Predicate Device

Predicate Device: MEVION S250i Proton Beam Radiation Therapy Device (K172848)

Regulation Number: 892.5050

Product Code: LHN

IV. Reference Device

Reference Device: P-Cure Proton Beam Therapy System (K221996)

Regulation Number: 892.5050

Product Code: LHN

V. Indications for Use

The MEVION S250-FIT Proton Beam Radiation Therapy Device is intended to deliver proton radiation treatment to patients with localized tumors or any other conditions susceptible to treatment by radiation. When the patient is in the fully seated position, the MEVION S250-FIT is indicated for treatment of patients with localized tumors and other conditions susceptible to treatment by radiation in the sites above the mid-chest or carina.

VI. Device Description

The MEVION S250-FIT Proton Beam Radiation Therapy Device is a proton beam radiation therapy system that provides a therapeutic proton beam for clinical treatment. It is designed to deliver a proton beam with the prescribed dose and three-dimensional dose distribution to the prescribed patient treatment site. The MEVION S250-FIT delivers radiation via a pencil beam (spot) scanning modality. In order to reach a target depth of 32cm in the patient, the accelerator is designed to produce a 230MeV beam.

The S250-FIT is comprised of 6 subsystems:

- Beam Generation System – generates the beam and directs it to the beam delivery system.
- Beam Delivery System – ensures that the therapeutic prescription parameters are properly delivered.
- Hardwired Safety System (HSS) – provides for system and beam delivery interlocking without the use of software
- Patient Positioning System – The Marie Device from Leo Cancer Care (K250970) allows for accurate and efficient positioning of the patient in a seated or perched position for treatment using an Upright Patient Positioner and 3D CT Scanner for Treatment Planning and Patient Registration.
- Structural Support/Alignment System – supports the beam generation and delivery systems and allows the fixed beam delivery to the single point in space (i.e., the Isocenter)

- System Software – controls the above subsystems (except the HSS) and provides interfaces to the system for the end-user.

VII. Comparison of Technological Characteristics with the Predicate

The Subject device is substantially equivalent to the previously cleared predicate device. Both systems provide a therapeutic proton beam for clinical treatment and have the same indications for use. Both systems are designed to deliver a proton beam from a treatment plan with a prescribed dose and dose distribution to a prescribed patient-based target. The systems have comparable specifications, with differences in the beam angle adjustment, patient positioner, and imaging. These differences between the systems do not raise different questions of safety or effectiveness and can be deemed substantially equivalent to the predicate device. The subject device positions the patient in a seated and perched position with the Leo Cancer Care Marie (K250970) device compared to the supine position used with the predicate system. These differences do not raise questions of safety or effectiveness and testing demonstrates substantially equivalent performance compared to the predicate. A table comparing the key features of the subject and predicate devices is provided below.

Device Feature	**Subject Device**	**Predicate Device**	**SE Comparison**
Trade Name	S250-FIT Proton Beam Radiation Therapy Device	S250i Proton Beam Radiation Therapy Device	-
Manufacturer	Mevion Medical Systems, Inc.	Mevion Medical Systems, Inc.	-
510(k)	K250986	K172848	-

Intended Use/ Indications	The MEVION S250-FIT Proton Beam Radiation Therapy Device is intended to deliver proton radiation treatment to patients with localized tumors or any other conditions susceptible to treatment by radiation. When the patient is in the fully seated position, the MEVION S250-FIT is indicated for treatment of patients with localized tumors and other conditions susceptible to treatment by radiation in the sites above the mid-chest or carina.	The MEVION S250i System is intended to deliver proton radiation therapy treatment to patients with localized tumors or other conditions susceptible to treatment by radiation.	The difference is that the S250-FIT Proton Beam Radiation Therapy Device includes a clarification, which specifies positional limitations for treatment sites for patients in the 'fully seated' position. This clarification does not alter the intended therapeutic use of the device. This clarification does not affect the safety and effectiveness of the device when used as labeled.
Patient Population	Adults, Pediatrics	Adults, Pediatrics	The Subject Device and the Predicate include both Adults and Pediatrics.
Proton Accelerator	230 MeV superconducting synchrocyclotron	230 MeV superconducting synchrocyclotron	The subject device and predicate device are identical, having same particle type, energy level, acceleration mechanism, beam delivery, magnetic field generation, and operational mode.
Usable Energy Range	30 - 230 MeV	30 - 230 MeV	The subject device and predicate device have identical usable energy range.
Beam Delivery Modality	Pencil Beam Scanning	Pencil Beam Scanning	The subject device and predicate device both utilize pencil beam scanning.
Beam Range in patient	0.8 g/cm^2 – 32.2 g/cm^2	0.8 g/cm^2 – 32.2 g/cm^2	The subject device and predicate device have identical beam range in patients.

Dose Rate	2Gy/Min	2Gy/Min	The dose rate for both the subject device and predicate device is 2Gy/Min.
Spot Distal Dose Falloff	The 80% - 20% distal dose falloff of any pristine Bragg peak in water is 0.5 cm or less	The 80% - 20% distal dose falloff of any pristine Bragg peak in water is 0.5 cm or less.	The Spot Distal Dose Falloff is identical for both the subject device and the predicate device.
Beam Spot Size	≤ 0.5 cm for maximum energy (depth) and no greater than 1.5 cm for minimum energy (depth)	≤ 0.5 cm for maximum energy (depth) and no greater than 1.5 cm for minimum energy (depth)	The beam spot size for the predicate and subject devices are identical.
Spot Range Accuracy	Within ± 0.1 g/cm^2 over all operational parameters of the system.	Within ± 0.1 g/cm^2 over all operational parameters of the system.	The spot range accuracy is identical for the predicate and the subject device.
Range Selection	Boron-carbide ceramic Range Shifter Plates	Polycarbonate Range Shifter Plates	There are minor changes to the range shifter from the S250i to the S250-FIT. Changes include modification to the Range Shifter plate material from polycarbonate to boron-carbide ceramic (with exception to two smallest plates).
Energy Modulation	Boron-carbide ceramic Range Shifter Plates	Polycarbonate Range Shifter Plates	There are minor changes to the range shifter from the S250i to the S250-FIT. Changes include modification to the Range Shifter plate material from polycarbonate to boron-carbide ceramic (with exception to two smallest plates).

Patient Positioner	6-axis Platform Mounted Upright Positioner	Multi-Axis Supine Positioner	The Subject Device and the predicate both feature multi-axis patient positioners. The Subject Device positions the patient upright. The Predicate Device positions the patient supine.
Maximum Load	330 lbs	400 lbs	The subject device and predicate device have differing maximum loads.
Imaging	Integrated CT supplied by Leo Cancer Care, ltd.	2D X-ray	Both subject and predicate devices utilize X-ray Imaging for Image Guided Radiotherapy.
Discrete Arc Planning	Yes	Yes; but not automatic sequencing of fields	Discrete Arc Planning is a new feature within the S250-FIT that was not present in the predicate device.
Remote Motion	Yes	No	Remote motion is a new feature within the S250-FIT device that was not present within the predicate device.

VIII. Summary of Performance Testing (Non-Clinical)

System and subsystem verification testing was performed to address aspects of the device design that have changed or that may have been impacted by the changes to the device design.

For subsystems or components that have been modified or are impacted by the S250-FIT configuration, Mevion repeated the original test protocols used for the Mevion S250i for testing S250-FIT to demonstrate substantially equivalent safety and performance.

Treatment Plans evaluating the clinical adequacy of the subject device and the predicate were evaluated for Intracranial, Head & Neck, Thoracic, Abdominal and Pelvic

(for perched and max-perched positions) targets. Radiation beam delivery was determined not to be compromised by organ positional or physiological changes resulting from upright patient orientation. Treatment Plans were reviewed for dosimetric coverage, preservation of OARs and overall clinical acceptability. The results of this study demonstrated substantial equivalence.

Standards Testing was completed in accordance with the following FDA-recognized standards:

Ion Beam

- IEC 60601-2-64 Edition 1.0 2014-09, Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment
- IEC 62667 Edition 1.0 2017-08, Medical electrical equipment - Medical light ion beam equipment – Performance characteristics

X-Ray/CT

- IEC 60601-2-68:2014 Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment
- IEC 60601-2-44:2016 Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
- IEC 60601-1-3:2008 + A1:2013+A2:2021 General Requirements for radiation protection in diagnostic x-ray equipment

Lasers

- IEC 60825-1 Edition 3, Safety of Laser Products – Part 1 Equipment Classification and Requirements

Interoperability testing was conducted following FDA Guidance, Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices - Guidance for Industry and Food and Drug Administration Staff, Issued September 2017. ANSI/AAMI/UL 2800-1:2022 including parts -1,-2, and -3 will be consulted for guidance.

Cybersecurity testing was conducted in accordance with ANSI/AAMI SW96:2023 and follow FDA Draft Guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Draft Guidance for Industry and Food and Drug Administration Staff, Issued April 8, 2022.

Software development and testing was performed in accordance with IEC 62304 Edition 1.1 2015-06 and FDA Guidance Document, Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff, Issued June 14, 2023.

Human Factors and Usability Testing was conducted according to IEC 62366-1:2015+A1:2020, IEC 60601-1-6 Edition 3.2 2020-07, FDA Guidance, Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff, Issued February 2016 and FDA Draft Guidance, Content of Human Factors Information in Medical Device Marketing Submissions.

System Testing

System level standards testing was conducted to show system compliance to:

- ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 [Incl. AMD2:2021], Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
- IEC 60601-1-2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-64:2014 Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment

Clinical Testing

- Not applicable.

IX. Substantial Equivalence Conclusion

The Mevion S250-FIT Proton Beam Radiation Therapy Device is substantially equivalent to the previously cleared S250i Proton Beam Radiation Therapy system. Both systems provide a therapeutic proton beam for clinical treatment and have the same intended use. Both systems are designed to deliver a proton beam set with a prescribed dose and dose distribution to a prescribed patient-based target, consistent with the facility's treatment planning system (TPS). The systems have the same beam performance specifications and utilize the same accelerator. Differences between the systems do not raise different questions of safety or effectiveness. To demonstrate substantial equivalence as well as safety and effectiveness, the same type of testing conducted to support the cleared S250i has been performed to verify and validate the Mevion S250-

FIT Proton Beam Radiation Therapy Device. Thus, the Mevion S250-FIT Proton Beam Radiation Therapy System is substantially equivalent.