



March 25, 2026

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

Re: K253406

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: October 23, 2025
Received: October 23, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

A handwritten signature in black ink that reads "Lora Weidner". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K253406

?

Please provide the device trade name(s).

?

S250-FIT Proton Beam Radiation Therapy Device

Please provide your Indications for Use below.

?

The MEVION S250-FIT 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.

Please select the types of uses (select one or both, as applicable).

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

?

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: K253406

Date: September 30, 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: S250-FIT Proton Beam Radiation Therapy Device (K250986)

Regulation Number: 892.5050

Product Code: LHN

This 510(k) is a modification of the Mevion Medical Systems previously cleared device to incorporate an optional 2D Image Verification Subsystem.

IV. 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.

V. Device Description

The 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.

This submission incorporates an optional subsystem for 2D image verification using oblique x-rays to verify patient alignment prior to beam delivery.

The S250-FIT is comprised of the following 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.

- Verification Imaging Subsystem (Optional) – 2D Oblique X-ray System that provides a secondary means of verification for patient alignment to the end-user. A separate software package, Verity is used to generate a 3D reconstruction and displays images for alignment.

VI. 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. The Subject device incorporates an optional 2D Verification Imaging System to be used to verify patient alignment prior to delivering treatment. This difference does 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	S250-FIT Proton Beam Radiation Therapy Device	-
Manufacturer	Mevion Medical Systems, Inc.	Mevion Medical Systems, Inc.	-
510(k)	K253406	K250986	-

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 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 subject device and predicate device are identical
Patient Population	Adults, Pediatrics	Adults, Pediatrics	The subject device and predicate device are identical
Proton Accelerator	230 MeV superconducting synchrocyclotron	230 MeV superconducting synchrocyclotron	The subject device and predicate device are identical
Usable Energy Range	30 - 230 MeV	30 - 230 MeV	The subject device and predicate device are identical
Beam Delivery Modality	Pencil Beam Scanning	Pencil Beam Scanning	The subject device and predicate device are identical
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 are identical
Dose Rate	2Gy/Min	2Gy/Min	The subject device and predicate device are identical
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 subject device and predicate device are identical

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 subject device and predicate device 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 subject device and predicate device are identical.
Range Selection	Boron-carbide ceramic Range Shifter Plates	Boron-carbide ceramic Range Shifter Plates	The subject device and predicate device are identical
Energy Modulation	Boron-carbide ceramic Range Shifter Plates	Boron-carbide ceramic Range Shifter Plates	The subject device and predicate device are identical
Patient Positioner	6-axis Platform Mounted Upright Positioner	6-axis Platform Mounted Upright Positioner	The subject device and predicate device are identical
Maximum Load	330 lbs	330 lbs	The subject device and predicate device are identical
Imaging (3D)	Integrated CT supplied by Leo Cancer Care, Ltd.	Integrated CT supplied by Leo Cancer Care, Ltd.	The subject device and predicate device are identical.
Imaging (2D) (Optional)	2D Oblique X-Ray System supplied by Mevion Medical Systems, inc.	-	The subject device includes an optional subsystem that allows for secondary verification imaging for patient positioning. The primary method of verification prior to treatment remains unchanged and the new 2D Imaging Option does not allow for the application of deltas to the UPP. The addition of this subsystem does not impact intended use or treatment, and does not raise new questions of safety or effectiveness.

Discrete Arc Planning	Yes	Yes	The subject device and predicate device are identical.
Remote Motion	Yes	Yes	The subject device and predicate device are identical.

VII. Summary of Performance Testing (Non-Clinical)

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.

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

Basic Electrical Safety and EMC

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

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 60601-1-3 Edition 2.2 2021-01 CONSOLIDATED VERSION General Requirements for radiation protection in diagnostic x-ray equipment
- IEC 60601-2-54 Edition 2.0 2022-09 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

Lasers

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

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.

Clinical Testing

- Not applicable.

VIII. Substantial Equivalence Conclusion

The S250-FIT Proton Beam Radiation Therapy Device is substantially equivalent to the previously cleared S250-FIT Proton Beam Radiation Therapy Device. The Subject device and the predicate have the same intended use and differences between the systems do not raise new questions of safety or effectiveness. Therefore, the S250-FIT Proton Beam Radiation Therapy Device is substantially equivalent.