Mevion Medical Systems, Inc.
% Mr. Thomas Faris
VP Regulatory and Quality Assurance, Management Representative
300 Foster St.
LITTLETON MA 01460

December 27, 2017

Re: K172848
Trade/Device Name: MEVION S250i
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: December 1, 2017
Received: December 4, 2017

Dear Mr. Faris:

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 (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. 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.

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 803); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Section 4

## Intended Use and Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K172848

Device Name
MEVION S250i

Indications for Use *(Describe)*

The MEVION S250i is intended to deliver proton radiation therapy treatment to patients with localized tumors or other conditions susceptible to treatment by radiation.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# Section 5

## 510(k) Summary or 510(k) Statement

# MEVION S250i, Proton Radiation Beam Therapy System Premarket Notification (510(k)) Summary

## Introduction

This document provides a high-level summary of the contents of the MEVION S250i Premarket Notification (510(k)), including a summary of the basis for the determination of Substantial Equivalence to the Predicate Devices.

This Premarket Notification (510(k)) Summary contains no confidential or trade secret information and is intended for full public disclosure and distribution. For addition information, please contact the Establishment's contact listed below, Thomas H. Faris.

## Premarket Notification Information

### Product Information

| | |
|---|---|
| Product Name | MEVON S250i<br>(Also called MEVION S250i with Hyperscan) |
| Common/Usual Name | Proton Radiation Beam Therapy System |

### Classification Information

| | |
|---|---|
| Classification Name | Charged Particle Radiation Therapy System |
| Product Code | LHN |
| CFR Reference | 21 CFR 892.5050 |
| Product Classification | Class II |
| Review Panel | Office of In Vitro Diagnostics and Radiological Health, CDRH |

### Establishment Information

| | |
|---|---|
| Submitter | Mevion Medical Systems, Inc. |
| Submitter Type | Manufacturer (no sterilization) |
| Submitter Address | 300 Foster Street Littleton, MA 01460 |
| Submitter Phone | 978-540-1500 |
| Submitter Fax | 978-540-1501 |
| Establishment Number | 3007087027 |
| Establishment Contact | Thomas H. Faris, Esq. |
| Contact Title | VP RA/QA |
| Contact Phone | 650-996-1192 |
| Contact Email | tfaris@mevion.com |

## MEVION S250i Intended Use Statement / Indications for Use

The MEVION S250i is intended to deliver proton radiation treatment to patients with localized tumors or any other conditions susceptible to treatment by radiation.

The Applicant Device has the same Intended Use / Indications for Use as the Predicate Devices: proton therapy for "… patients with localized tumors or any other conditions susceptible to treatment by radiation. Similarly, the Indications for Use are identical, as the conditions for treatment and potential patient populations remain as described in the Intended Use statement.

## Description of the Product / Technological Characteristics

The MEVION S250i is a proton beam radiation therapy system, which provides a therapeutic proton beam for clinical treatment. It is designed to deliver a proton beam with the prescribed dose and dose distribution to the prescribed patient treatment site. The MEVON S250i is a modern proton therapy system combining a patented, gantry-mounted proton source and a precision scanning beamline with a highly integrated, image-based workflow. The proton accelerator is a superconducting synchrocyclotron. The synchrocyclotron source generates protons of energy 230 MeV and is mounted in a high-precision concentric gantry system that rotates and points at treatment isocenter at all times. The system components include a Beam Generation System, Beam Delivery System, Structural Support and Alignment System, Patient Positioning System, Control System Software, and a Hard-wired Safety System (HSS).

A Beam Generation system, comprised of a 230MeV Synchrocyclotron, is used to generate a clinical useful proton beam with sufficient and adjustable beam current, range, and stability. The Beam Generation system includes a Superconducting Magnet, Synchrocyclotron, Ion Source, Radiofrequency System, Beam Extraction System, and Vacuum and Cooling Systems.

A Beam Delivery System measures, modifies, and shapes the proton beam so that delivered proton beam conforms to the prescribed target shape and dose. The Beam Delivery System includes Scanning Beam Forming, Dosimetry, and Treatment Nozzle subsystems. The HYPERSCAN pencil beam Scanning Beam Forming System consists of the scanning magnet, beam control, dosimetry, ion chambers, the energy modulation system (range shifter), and the adaptive aperture collimation (dynamic Micro-MLC) system.

A Patient Positioning System, the same as in the cleared S-250 (K120676), includes a Treatment Couch and offers a 2D and 3D patient setup system



300 Foster Street, Littleton, MA 01460 978.540.1500

(Called “Verity”). The robotic couch enables high precision 6 degree of freedom patient positioning. The Patient Setup System (Verity) is the on-board patient imaging based position correction system for the MEVON S250 Series. In its 2D/3D mode, the Verity System uses in-room orthogonal radiographic X-rays, and in 3D/3D mode, it uses in-room CT imaging, to match the patient images to the treatment planning images to calculate couch corrections required to align the patient to the treatment isocenter.

A structural support and alignment system includes a treatment gantry and treatment room enclosure. The previously cleared MEVION S-250 included the same Cyclotron Gantry support system, while the IBA Proteus ONE maintains the cyclotron in an adjacent cyclotron room.

Control System Software controls and coordinates the operation of all subsystems of the device, provides a user interface to the MEVION S250i, and ensure intended treatment setup and delivery of the treatment. Software updates have been made to facilitate the new Beam Scanning delivery modality for the MEVION S250i.

A Hard-wired Safety System (HSS) provides system performance monitoring and automatic interlocks that inhibit or interrupt beam, system motion, and/or other machine activity when machine performance may not satisfy defined treatment or operating parameters.

The above technological characteristics of the Applicant Device are Substantially Equivalent to the Predicate Devices, which demonstrate similar and equivalent design.

## Predicate Devices

The MEVION S250i is Substantially Equivalent to the MEVION S-250 (K120676). The product design was changed to add a Beam Scanning modality configuration in addition to the previously cleared Double Scatter modality. These changes are not new or novel and raise no new issues of safety or efficacy. The Ion Beam Application’s (IBA’s) Proteus One (Proteus 235) is a substantially equivalent and cleared (K152224) device that offers a Beam Scanning modality. The Technical Characteristics of the new MEVION S250i Beam Scanning Modality are Substantially Equivalent to the IBA Proteus One.



300 Foster Street, Littleton, MA 01460 978.540.1500

## Substantial Equivalence Comparison Matrix

| Characteristic | IBA Proteus One (Proteus 235) | MEVION S-250 | MEVION S250i |
|---|---|---|---|
| **Device** | **Predicate Device** | **Predicate Device** | **Applicant Device** |
| **510(k) Number** | **K152224** | **K120676** | **N/A- Proposed Device** |
| **Intended Use** | The Proton Therapy System - Proteus 235 (brand names: Proteus Plus and Proteus ONE) is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation. The PTS may include a fixed small beam treatment room dedicated to the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation localized to the head and neck | The S-250 is intended to deliver proton radiation treatment to patients with localized tumors or any other conditions susceptible to treatment by radiation. | The MEVION S250i is intended to deliver proton radiation treatment to patients with localized tumors or any other conditions susceptible to treatment by radiation. |
| **Energy (MeV) at Patient** | 70-230 MeV | 70-250 MeV | 70-230 MeV |
| **Particle** | Proton | Proton | Proton |
| **Accelerator** | 230 MeV superconducting synchrocyclotron | 250 MeV superconducting synchrocyclotron | 230 MeV superconducting synchrocyclotron |
| **Beam Time Structure** | Pulsed Beam at 1000 Hz | Pulsed Beam at 500 Hz | Pulsed Beam at 750 Hz |
| **Ion Source** | Cold Cathode PIG Ion Source | Cold Cathode PIG Ion Source | Cold Cathode PIG Ion Source |
| **Type of Coils** | Superconducting Coils | Superconducting Coils | Superconducting Coils |
| **Cooling Method** | Chilled water and Gifford-McMahon Cryocoolers | Chilled water and Gifford-McMahon Cryocoolers | Chilled water and Gifford-McMahon Cryocoolers |
| **Beam Transport and Switching System** | Beam transport system from the dedicated cyclotron containment vault that transports the proton beam to the treatment room. | No beam switching or transport system required. An isocentric gantry mounted cyclotron serves a single treatment room with a direct beam line | No beam switching or transport system required. An isocentric gantry mounted cyclotron serves a single treatment room with a direct beam line |



300 Foster Street, Littleton, MA 01460 978.540.1500

| Characteristic | IBA Proteus One (Proteus 235) | MEVION S-250 | MEVION S250i |
|---|---|---|---|
| **Device** | **Predicate Device** | **Predicate Device** | **Applicant Device** |
| **Beam Transport Magnets** | Yes | No external steering magnets required | No external steering magnets required |
| **Treatment Configuration** | Compact Single Room Treatment Machine | Compact Single Room Treatment Machine | Compact Single Room Treatment Machine |
| **Treatment Table** | Robotic Couch with 6 degrees of freedom | Robotic Couch with 6 degrees of freedom | Robotic Couch with 6 degrees of freedom |
| **Patient Positioning System** | Radiographic or CT assisted positioning system | Radiographic or CT assisted positioning system | Radiographic or CT assisted positioning system |
| **Bean Delivery Modality** | Pencil Beam Scanning | Double Scatter | Pencil Beam Scanning |
| **Range in patient** | 5 g/cm$^2$ – 32 g/cm$^2$ | 5 g/cm$^2$ – 32 g/cm$^2$ | 0.8 g/cm$^2$ – 32.2 g/cm$^2$ |
| **Dose Rate** | > 2Gy/Min | > 2Gy/Min | > 2Gy/Min |
| **Spot Size** | ≤ 15 mm on the range of energies | Not Applicable | ≤ 5 mm at maximum energy (depth) to 15 mm at minimum energy (depth) |
| **Spot Position Accuracy** | ≤ 15% of beam sigma or < to 1.5 mm | Not Applicable | ≤ 10% of beam size, max 0.9 mm |
| **Range Selection** | Beryllium Wedge Absorber | Carbon Wedge Absorber | Polycarbonate Range shifter plates |
| **Energy Modulation** | Beryllium Wedge Absorber | Modulation wheels | Polycarbonate Range shifter plates |
| **Dose Modulation** | Individual Spot Dose Control | Not Applicable | Individual Spot Dose Control |
| **Planar Beam Shaping** | None (Scanning Beam) | Brass Apertures | Dynamic Micro Multi-leaf Collimator |
| **Safety System** | Hard-wired relay-based interlock system and user activated shut-offs | Hard-wired relay-based interlock system and user activated shut-offs | Hard-wired relay-based interlock system and user activated shut-offs |



300 Foster Street, Littleton, MA 01460 978.540.1500

## Discussion of the Design Change and Substantial Equivalence

The design change that triggered this submission is the offering of a new MEVION S250i Beam Delivery modality. Beam Scanning is a configuration option in addition to the Double Scatter Beam Delivery previously cleared by the FDA in K120676. Beam Scanning is a common Beam Delivery modality currently in use. Ion Beam Applications' (IBA's) Proteus One (Proteus 235) has been previously cleared by the FDA in K152224 and is compared as a Predicate Device in this Substantial Equivalence Analysis. In both the Applicant and IBA Predicate Device, Beam Scanning Magnets are used to create a proton Scanning Beam and range shifting/beam modulation technology, comprised of energy absorbing materials placed in the beam path, are used to produce a pencil beam scanning beam that can accurately deliver therapeutic radiation to desired treatment volumes and dose levels. The previously cleared S-250 design uses Brass Apertures to shape the planar treatment beam. The MEVION S250i incorporates a dynamic micro-MLC ("Adaptive Aperture") to provide a very accurately contoured edge for treatment of the target volume. The Adaptive Aperture provides treatment beam collimation in the same manner as the MEVION S-250 brass apertures.

## Verification and Validation / Risk Management

Risk Management and Verification and Validation activities have been employed to ensure safe and effective implementation of the pertinent product Performance Requirements and technologies.

Risk Management

The MEVION S250i is a medical device that is to be used in a treatment or therapy setting under the supervision and control of appropriately trained health care professionals who are responsible for the correct performance and delivery of radiation therapy. The MEVION S250i System Hazard Analysis was performed to determine and evaluate all potential health and safety hazards associated with treatment system use and operation. All foreseeable system hazards, effects, and causes have been evaluated to determine necessary and appropriate risk mitigations. Verification and validation, risk mitigation traceability, design review, and final reporting have been performed to ensure effective implementation of the stated risk mitigations.



300 Foster Street, Littleton, MA 01460 978.540.1500

Verification and Validation

Design Reviews have been held at pertinent phase passage points to review and validate the fulfillment of all of the phase requirements and deliverables, always including product safety and efficacy consideration. Verification and Validation Protocols have been executed to ensure adequate testing of all defined product design requirements and specifications. A Traceability Matrix has been created to ensure fulfillment of all design requirements. Verification and Validation Test Reports have been created to evaluate the acceptability of test results and product module / product release preparedness. All applicable design and development and verification and validation activities and records have been completed to ensure safety and efficacy of the final MEVION S250i Proton Beam Radiation Therapy System

Verification and Validation Testing Performed:

- Implementation of Design Changes
- Regression Testing, as appropriate
- Satisfaction of all Performance Requirements
- Software Verification and Validation
- Electrical Safety and Electromagnetic compatibility (EMC)

All technological characteristics and performance requirements identified in the Substantial Equivalence Comparison have been tested to ensure success of the design implementation. There are no new or different issues of safety or efficacy introduced by the stated design change. Risk Management and Verification and Validation activities confirm that the MEVION S250i is Substantially Equivalent to the Predicate Devices.

Pertinent Risk Management and Verification and Validation Records have been included in the Premarket Notification (510(k)), evidencing the conclusion of Substantial Equivalence.



300 Foster Street, Littleton, MA 01460 978.540.1500

## Conclusion of Substantial Equivalence

The MEVION S250i is Substantially Equivalent to the MEVION S-250 and the IBA Proteus One:

- The predicates are legally marketed, cleared by the FDA by Premarket Notification
- There are no new or novel Technical Characteristics
- The Intended Use and Indications for Use are identical
- There are no new or changed issues of safety or efficacy for consideration
- Risk Management and Verification and Validation data and records demonstrate Substantial Equivalence



300 Foster Street, Littleton, MA 01460 978.540.1500