K120676

JUN - 4 2012

MEVION medical systems

February 29, 2012

S-250, Proton Radiation Beam Therapy System Premarket Notification (510(k)) Summary

Introduction

This document provides a summary of the safety and effectiveness information contained in the Mevion S-250 Proton Radiation Beam Therapy System Premarket Notification (510(k)). 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

1. Previous Notificaton Information:
   a. Previous Submission #: I060690, K093347, K082165
   b. Previous FDA Clearance Date None
   c. Product Name S-250

2. Product Information
   a. Product Name S-250
   b. Common/Usual Name Proton Radiation Beam Therapy System

3. Classification Informaiton
   a. Classfication Name Charged Particle Radiation Therapy System
   b. Product Code LHN
   c. CFR Reference 21 CFR 892.5050
   d. Product Classfication Class II
   e. Review Panel Office of In Vitro Diagnostic Device Evaluation and Safety

MEVION medical systems

4. Establishment Information

a.	Submitter	Mevion Medical Systems
b.	Submitter Type	Manufacturer (no sterilization)
c.	Establishment Number registered	TBD (not registered yet, to be post submission)
d.	Establishment Contact	Thomas H. Faris
e.	Contact Title	VP RA/QA
f.	Contact Phone	650-996-1192
g.	Contact Email	tfaris@Mevion.com

S-250 Intended Use Statement

The S-250 is intended to deliver proton radiation treatment to patients with localized tumors or any other conditions susceptible to treatment by radiation.

S-250 Indications for Use Statement

The S-250 is a medical device indicated for the delivery of radiation for the treatment of patients with localized tumors or other conditions susceptible to treatment by radiation.

Description of the Product / Technological Characteristics

The S-250 is a low cost, one-room integrated device designed to administer proton radiation treatments to patients through delivery of a predetermined radiation dose to a pre-determined three dimensional treatment target volume in a manner that protects the patient, and hospital staff, from unnecessary exposure to radiation and other hazards.

The S-250 design requires a very compact proton accelerator which is supported on a rotating gantry such that a proton treatment beam can be directed toward the rotational center of the gantry over a range of about 180 degrees (straight up to straight down). The gantry holds the cyclotron at a large enough distance from the rotating arm(s) that a full treatment room floor can be extended around the treatment center and a treatment couch can support a patient over a large rotational (couch) range at isocenter.

The system will be a completely integrated system incorporating all functionality necessary to efficiently treat patients with proton beams. As such it incorporates near real time radiographic based patient alignment and coupled patient support

devices (couch) with broad flexibility for supporting the patient relative to the treatment beam. The couch is capable of six-degree-of-freedom adjustment and be able to rotate about a vertical axis in a range of about 270 degrees, so as to provide full coverage of beam directions typically used in radiation therapy

To keep high precision of alignment of the field specific device (range compensator and apertures) to the patient, these devices will be supported on a separate gantry, close to the treatment center and not physically connected to the large gantry supporting the cyclotron. This will lighten the aiming requirements for the large gantry.

The S-250 is a proton beam irradiation 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 as provided by a separately marketed Treatment Planning System (TPS) not distributed by Mevion Medical Systems. The S-250™ is comprised of two main components. One is a beam delivery system whose primary responsibility is to ensure that the prescription parameters are properly delivered. The other is the beam generating system whose function is to generate the proton beam and direct it to the beam delivery system.

Technological Comparison:

The Mevion S-250 does not require new technical innovations beyond existing technologies, as described below:

High field magnet - A magnetic field of sufficient strength everywhere in the cyclotron to meet the requirements for reasonable single treatment room implementation. Magnets of this field strength are made with superconducting wire.

Radiofrequency System - Rapidly varying radiofrequency systems have been constructed for synchrocyclotrons in the past.

Ion Source and Cyclotron Central Region - The Ion Source / Central region takes into account the very small radius of curvature of the low energy ion beam in very high magnetic fields. This will require that any physical object spanning the acceleration plane to be much smaller than the orbit to orbit spacing achieved with the given radiofrequency power / voltage.

Beam Extraction System - Follows the design of previous synchrocyclotrons and superconducting cyclotrons. However this will be the highest magnetic field cyclotron so that design of the magnetic field perturbations with machined steel magnet pole pieces will be more constrained than in prior experience.

The Vacuum System - designed using conventional components.

MEVION medical systems

The Gantry - constructed of steel and aluminum components fastened together by welds and/or bolts in conventional fashion.

Field Shaping - a straightforward design extension of the double scattering systems developed by Gottschalk et al at the Harvard Cyclotron.

Dosimetry – designed and constructed following conventional radiotherapy beam dosimetry standard techniques.

C-Inner Gantry, Applicator and Applicator Changing System – does not require any advanced design or fabrication techniques.

Radiographic systems - straightforward adaptation of existing digital radiographic systems (x-ray tubes, generators, and amorphous silicon imaging panels.

Predicate Devices and Substantial Equivalence Determination

1) Harvard Cyclotron Lab
   - Harvard Cyclotron
   - Pre-Amendment

2) IBA
   - Proteus 235 Proton Therapy System
   - K060695, K053641,K061913, K053641, K983332, K983024

3) LLUMC, Fermi National Accelerator Lab
   - Loma Linda University Proton Therapy System
   - K872369

4) Indiana University Cyclotron Facility
   - Proton Therapy System
   - K062891

5) Hitachi
   - PROBEAT
   - K053280

6) Varian
   - pt2 varian proton therapy system
   - K101294

The S-250 and the device predicates produce a clinically viable proton beam to be delivered to provide radiation therapy. The S-250 is Substantially Equivalent to the

above listed devices. The proton therapy systems have substantially the same Intended Use and principles of operation, and are substantially equivalent in terms of performance and technological characteristics. All of these medical devices comprise proton beam production technology and delivery systems that localize proton radiation at the patient's treatment site. Patients are put into correct treatment location by positioning and targeting systems.

Like each of the predicate devices, the S-250 is designed to produce and deliver a proton radiation beam for patient treatment, when radiation therapy is indicated as an appropriate course of treatment. And, equivalent to predicate Indications For Use statements, the S-250 is intended for the therapeutic delivery of proton beam radiation for the treatment of localized tumors or other conditions that are susceptible to radiotherapy treatment.

There are no technological differences between the S-250 and its predicate devices that raise new questions of safety or efficacy. Performance data demonstrates that the S-250 is as safe and effective as the predicate devices listed herein. Thusly, the S-250 is substantially equivalent to the listed predicate devices.

Clinical Demonstration of Efficacy

The S-250 Proton Beam Radiation Therapy System offers no additional or changed diagnostic or therapeutic claims beyond the stated predicate devices. Therefore, demonstration of clinical efficacy is not a required element of this premarket notification. However, this Premarket Notification includes a Clinical Data Evaluation Report that summarizes peer-reviewed literature related to the clinical efficacy and safety proton beam radiation therapy systems.

Device Safety

The S-250 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 S-250 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. Risk analysis shall be evaluated incident to all product design and development changes. The design and development teams have determined that the product does not pose unreasonable health or safety risk to patients, users, other bystanders.

MEVION
medical systems

Quality System

The Mevion quality system is committed to creating and continually improving quality products, processes, and services to promote safety, effectiveness, and customer satisfaction. Mevion Medical Systems seeks to continually strive for more efficient and effective processes, as well as comply with regulatory requirements. All employees receive extensive training and management holds high the concept of a quality culture. The company takes great pride in the value that is contributed to its products, processes, and eventually to be realized by its customers and their patients.

The Mevion Medical Systems' quality system was developed and maintained in compliance with the following standards and regulations:

- FDA's Quality System Regulations
- ISO 9001
- ISO 13485
- ISO 62304
- ISO 14971
- 93/42/EEC – The Medical Device Directive (MDD)

Verification and Validation Testing

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 Plans have been created to define the overall plan for completing product/project modular, integration, and full system testing and assessment. Verification and Validation Protocols have been prepared 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 are 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 S-250 Proton Beam Radiation Therapy System (or will be completed prior to submission of the applicable records).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Thomas H. Faris
Vice President, RA/QA
Mevion Medical Systems, Inc
300 Foster Street
LITTLETON MA 01460

JUN - 4 2012

Re: K120676
Trade/Device Name: S-250 Proton Beam Radiation Treatment System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: May 23, 2012
Received: May 25, 2012

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120676

Device Name: **S-250 Proton Beam Radiation Treatment System**

Indications for Use:

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 S-250 is a medical device indicated for the delivery of radiation for the treatment of patients with localized tumors or other conditions susceptible to treatment by radiation.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120676