

JUL 10 2014

K132919
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510(k) SUMMARY

Ion Beam Applications S.A.

13 September 2013

Applicant

Ion Beam Applications S.A.

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Iba

Classification Name

Medical charged-particle radiation therapy systems. (21 C.F.R. §892.5050)

Predicate Device

The IBA Proton Therapy System – Proteus 235 (PTS) is substantially equivalent to the previously cleared IBA proton therapy system (K101508). The current PTS and its predicate device have the same intended use and principles of operation, and are substantially equivalent in terms of performance and technological characteristics.

Like its predicate IBA PTS device, this modified PTS is a device designed to produce and deliver a proton beam for treatment of a patient. As its predicate device, it is intended for use in the therapeutic application of a proton beam for the treatment of localized tumours or other diseases that are susceptible to treatment by radiation.

The technological aspects of a patient treatment consist of protons generated by the beam supply equipment, directed to the patient's treatment site by the beam delivery system. The patient is put into the correct position relative to the beam by a positioning system. The current IBA Proton Therapy System - Proteus 235 and its predicate device both consist of a beam production equipment which generates the beam used by a beam delivery systems including a patient positioning system.

The predicate device also provides the same or substantially equivalent functions, characteristics, and accessories as does the currently modified PTS.

Indication for Use

The PTS 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 indication for use is identical to the one of the predicate device.

Pre-market notification description

The change introduced in the IBA Proton Therapy System - Proteus 235 and described in this filing is the availability of a new IBA 220° Compact Gantry. The IBA 220° Compact Gantry combines the following advantages:

- Uncompromised positioning treatment options provided by a continuously adjustable treatment angle combined with 6° freedom of movement offered by the patient positioner. All treatment angle can be achieved;

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- The most compact gantry design ever developed for proton therapy, while still enabling easy patient access and non coplanar treatments.

Description of the device

The device corresponds to the previously cleared IBA proton therapy system (K101508) with the addition of a compact Gantry Beam line designed to produce and deliver a proton beam from various directions in a range of 220° for the treatment of patients.

Technological Characteristics

The IBA Proton Therapy System – Proteus 235 is designed to: (1) create and deliver the proton beam to the patient treatment location; (2) produce a transverse and longitudinal dose distribution appropriate for the patient's treatment; and (3) deliver the designated dose to the patient's treatment site. The PTS has two primary components: (1) the beam supply equipment, which directs the proton beam to the patient's treatment site within the patient treatment location and ensures that the clinical functions are properly and safely accomplished; and (2) the beam supply equipment, which includes a cyclotron, an energy selection system and a delivery system to produce the proton beam and deliver it to the patient treatment locations. In addition to these primary components, the PTS includes a Therapy Safety System to protect against unsafe conditions, having both automatic and manual controls to shut down the PTS in the event that any problem occurs; and a computer-based Therapy Control System which controls the parameters of the proton beam.

The change in the device that triggered this submission is the introduction of a Compact Gantry Beam Line (CGBL), which consists of:

- Another type of rotating isocentric gantry called Compact Gantry. Like other gantries, already part of the current Proteus 235, the CGBL supports a beam line and an associated nozzle supporting the scanning delivery technique, plus it can optionally integrate the energy selection system for a one-room configuration

The new Compact Gantry Beam Line modification is a simplification of the already existing 360° gantry beam line.

The changes are mainly limited to the gantry components and some of its interfaces.

Compared to the beam line with a 360° gantry, the radius of the compact gantry beam line is reduced, but the modified product does not induce changes nor any new limitations for clinical use (and therefore all existing clinical evidence remains valid):

a treatment fraction is still composed of one or more treatment fields where the proton beam will be pointed to the patient's tumor from one or more incidence angles. Those incidence angles are defined by both the direction of the beam realized by the gantry and the position and orientation of the patient support. To realize a particular incidence angle with respect to the patient, different combinations of gantry angles and patient positioner configurations are possible. Treatment rooms equipped with a 360° rotating gantry, promote gantry movements rather than patient support system movements. The compact gantry will use additional top rotations to cover the same range of beam incidences with respect to the patient in coplanar treatments.

With the CGBL, the Pencil Beam Scanning delivery technique is the delivery technique of choice. It allows intensity modulated proton therapy which is the most advanced technique to treat in proton therapy today. The fact of supporting one delivery technique results in decreasing the size of the nozzle which is beneficial for the access around the patient. Despite the maximum field size has been decreased to 24 cm x 20 cm, the same tumor size coverage can be guaranteed as in the 360° gantry beam line by using matching fields.

As for the previously cleared IBA proton therapy system, the CGBL is equipped with a patient positioning imaging system. With the CGBL, the nozzle is equipped with an Imaging Equipment insertion mechanism composed of 2 opposed moveable arms that can hold imaging equipment. These arms can be extracted from and retracted into the nozzle. Integrated with the appropriate imaging system (internal/external system) this allows planar X-ray imaging. In addition, thanks to the capability of pre-programmed gantry motion without continuous activation by the user, the compact gantry beam line is ready to support volumetric imaging at isocenter.

In conclusion, based on the above description, the predicate device has been modified as follows:

- a smaller gantry structure by reducing the angular range
- optionally a shorter beamline by integrating the energy selection system into the beamline on the gantry for a one-room configuration
- a smaller nozzle size by including only Pencil Beam Scanning delivery technique and reducing field size

The risk management approach that has been applied for the development of the Compact Gantry Beam Line is described in MID 38870. As described in this document, Risk Analyzes have been performed to identify possible risks associated with the Compact Gantry Beam Line and define appropriate risk mitigations. The main mitigation principles are already applied in the existing beam lines 360°.

Comparison table to predicate device

The following table gives an overview of the main characteristics of the conventional gantry which is already part of the IBA Proton Therapy System – Proteus 235 versus the Compact Gantry Beam Line



Table 1: Overview of the main characteristics of the 360° gantry beam line versus Compact Gantry Beam Line

Characteristic	360° Gantry Beam Line	Compact Gantry Beam Line
Angular position range	360°	220°
Isocenter accuracy (mechanical sphere of confusion radius)	1 mm	1 mm
Maximum rotation speed	1 rpm	1 rpm
Angle to get max speed	≤30°	≤ 30°
Maximum braking angle	5°	3°
Mechanical Angular repeatability	0.25°	0.25°
Brakes	Fail Safe	Same
Control for treatment mode	Multiple Access Point	Same
Motion modes	Goto, Jog	Goto, Jog, Trajectory
Treatment volume brought at isocenter	100 cm X 50 cm X 40 cm	100 cm X 50 cm X 40 cm
Collision prevention	By PPS load cell & proximity detection algorithm	By PPS load cell, proximity detection algorithm and sensors
Beam Range in Patient (Tissue depth)	Pencil Beam Scanning 0.5 to 32 cm	Pencil Beam Scanning 0.5 to 32 cm
Field size	30 cm x 40 cm	24 cm x 20 cm
Beam Distal Fall Off	≤0.25 g/cm ² above the physical limit	Same
Spot Size	≤ 15 mm on the range of energies	Same
Spot Position accuracy	≤ 15 % of beam sigma or < to 1.5 mm	Same
Effective SAD	≥ 2m	Same
Irradiation time	≤2 minutes for delivering 2Gy to 1L volume (10 x 10 x 10 cm ³)	Same

Impact on the existing IBA Proton Therapy System – Proteus 235

The predicate device architecture is not modified. The impacts are limited to some very specific areas.

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- A new beam line configuration is added to the product. When there are multiple rooms connected to the source (accelerator), it shall be possible to switch the beam to the Compact Gantry Beam Line (same principle as in Proteus 235 predicate device).
- The building is adapted in order to offer the appropriate structural and shielding interface with the Compact Gantry Beam Line.
 - Nevertheless, there are no changes in the gantry fixation technology to the building structure (anchors), the only adaptations are the smaller room dimensions and the interface dimensions due to the specific configuration.
- The Beam Line equipments (magnets, monitors) use the same technology and are adapted to the specific Compact Gantry Beam Line configuration (E.g: beam trajectories, interface assembly).
- The specific equipments required for the energy selection system (ESS) are optional on the gantry depending on the treatment center configuration

Conclusion

The new Compact Gantry fulfills the same primary functions as the 360° Gantry.

- It provides an isocentric rotating structure that rotates the beam axis in a plane perpendicular to the rotation axis, through a common isocenter within the required precision.
- It supports the movable portion of the beam transport line, a nozzle and an Imaging Equipment Insertion mechanism.
- It guarantees the same patient clearance as with the 360° gantry.
- It allows reaching the same clinical performances.



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

July 10, 2014

Ion Beam Application S.A.
% Mr. Bruce D. Armon, Partner
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PHILADELPHIA PA 19102

Re: K132919

Trade/Device Name: Compact Gantry Beam Line
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: February 10, 2014
Received: February 11, 2014

Dear Mr. Armon:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K132919

Device Name: Proton Therapy System – Proteus 235

Indications for Use:

The PTS 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.

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

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

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)



Division Sign-Off
Office of In Vitro Devices and Radiologic Health

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