Iba

K100766

510(k) SUMMARY

Ion Beam Applications S.A.

11 February 2010

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Applicant

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IBA

Classification Name

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

Predicate Device

The PTS is substantially equivalent to the previously cleared IBA proton therapy system (K983024). 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. Also like 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 predicate device also provides the same or substantially equivalent functions, characteristics, and accessories as does the currently modified PTS. All these devices are comprised of beam production equipment which generates the beam used by the beam delivery systems.

The technological aspects of a patient treatment consist of protons generated by the beam production 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.

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.

Description of the device modifications

The scope of this 510(k) submission comprehends a fixed beam treatment room customised for small beams that can accommodate sitted treatment.

Technological Characteristics

The device 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 delivery equipment, which directs the proton beam to the patient's treatment site within the patient treatment location and ensures the patient critical functions are properly and safely accomplished; and (2) the beam production equipment, which includes a cyclotron and 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 problems occur; and a computer-based Therapy Control System which controls the parameters of the proton beam.

Following the successive changes to the original 510(k) submission, several features have been already added:

(1) PPVS (K053641): The Patient positioning verification system (PPVS) is interfaced to a Treatment Planning System (TPS) or an Oncology Information System (OIS) for downloading the treatment plan and the associated Digitally Reconstructed Radiographs (DRR) from the TPS in DICOM format;

(2) SIS and US (K060695): addition of 2 treatment modes. The Single Scattering (SIS) technique is dedicated to the irradiation of fields smaller than seven centimetres, the Uniform Scanning (US) technique is an active technique for spreading beam in a transversal direction to large irradiation fields;

(3) IOIS (K061913) - An automatic network-based interface between an Oncology Information System (OIS) to the PTS for the input of patient information, which information initially is entered into the OIS by means of a Graphical User Interface has been added.

(4) Pencil Beam Scanning (K082416) - The pencil beam scanning is defined as the act of moving a charged particle beam of particular properties and/or changing one or more of the properties of that beam (e.g. Intensity, size, position, etc.). The goal of this beam delivery is to deliver the appropriate proton fluence according to a prescription. This prescription provides a map of the fluence that is necessary to deliver at each location on the target. Thus the beam is moved to each location on the target and the appropriate fluence is deposited at each location.

(4) Robotic PPS (K083058) – The PTS includes new PPS. It is a *SCARA-type* arm robot. The X- and Y-translations from the current PPS have been replaced by two rotations around vertical axes. The vertical motion (Z-axis) from the current PPS remains a translation in the Robot PPS.

(5) Proteus RTT and patient gantry access upgrade (K091629) – The Proteus RTT and patient gantry access upgrade consists of a redesign of the gantry patient enclosure (PE) and an associated technology update of the PTS interlock controller

(6) Inclined beam line (K092796) - The scope of the change is an inclined beam line which is a simplied gantry that accommodates only two beam orientations at 30° and 90°.

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

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JUL 21 2010

Re: K100766
Trade/Device Name: IBA Proton Therapy System – Proteus 235
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LNH
Dated: July 1, 2010
Received: July 2, 2010

Dear Dr. Reiss:

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,

Donald J. St.Pierre
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

510(k) Number (if known): K

Device Name: IBA PROTON THERAPY SYSTEM - PROTEUS 235

Indications For Use:

"The Proton Therapy System - Proteus 235 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 treatment of patients with localized tumors and other conditions susceptible to treatment by radiation localised to the head and neck."

Prescription Use _X_____ AND/OR Ove r-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 IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100760