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Special 510(k) SUMMARY

for Ion Beam Applications' Proton Therapy System Device Modification - K053641

Ion Beam Applications S.A.

Applicant

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Classification Name

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

Predicate Devices

The PTS with the Device Modification described below is substantially equivalent to the previously cleared Loma Linda University Medical Center ("Loma Linda") Proton Beam Therapy device (K872369), the Harvard University Cyclotron Laboratory Proton Beam Therapy device, a pre-1976 device and the Ion Beam Appliacionts (IBA) Proton Therapy System (K983024) The PTS with the Device Modification and its predicate devices have the same intended use and principles of operation, and are substantially equivalent in terms of performance and technological characteristics.

Intended Use

The PTS with the Device Modification 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.

Technological Characteristics K053641

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.

Substantial Equivalence Discussion

The PTS with the Device Modification is substantially equivalent to the Loma Linda (K872369), IBA (K983024) and Harvard Cyclotron Laboratory ("HCL") proton therapy devices. The HCL is a pre-1976 device that was constructed in 1949.

Like its predicate devices, the PTS with the Device Modification is a device designed to produce and deliver a proton beam for treatment of a patient. Also like its predicate devices, it is intended for use in the therapeutic application of a proton beam for the treatment of localized tumors or other diseases that are susceptible to treatment by radiation.

The predicate devices also provide the same or substantially equivalent functions, characteristics, and accessories as does the PTS with the Device Modification. All these devices are comprised of beam delivery systems which shape, direct, and monitor the protons delivered to the patient. They are also 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 shaping system which is either mounted on a rotatable gantry, or in a fixed position. The patient is put into the correct position relative to the beam by a positioning system.

The facilities include patient treatment rooms, with each having a different number of rooms. The PTS device may service three to seven rooms, the Loma Linda predicate has four rooms and the HCL predicate has two. Like the predicate Loma Linda and HCL devices, the PTS provides fixed beam treatment stations. The PTS also includes treatment rooms which have isocentric/rotatable gantries similar to those used in the Loma Linda facility, but the space enclosed by the gantry is larger than at Loma Linda so that the patient can be rotated horizontally, as at HCL, allowing more choice of treatment direction.

K053641

The PTS and predicate Loma Linda devices are equipped with nozzles that provide beam scattering and beam scanning; the nozzles for the HCL predicate use beam scattering. All three devices have beam-limiting collimators and range verifiers.

The Device Modification

This Device Modification submission describes a necessary change in the Patient Positioning Verification System (PPVS). In the original 510(k) system that was cleared for marketing, referred to above (K983024), the patient positioning devices involved stand-alone hardware and the software for calculating a 6-axis patient positioning correction vector. Once that calculation was completed, the positioning correction vector had to be set manually in the proton therapy user interfaces.

With this Device Modification, the process will be similar to that in the original submission. The modification is that the Patient Positioning Verification System (PPVS) will be 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. This contrasts with the original submission that transferred the PPVS via file servers or by using memory sticks. For this filing, we name the PPVS "DICOM Interfaced PPVS System."

This Device Modification primarily involves software changes, while the hardware generally is unchanged.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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JAN 24 2006

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Re: K053641
Trade/Device Name: Proton Therapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: December 29, 2005
Received: December 30, 2005

Dear Dr. Baelen:

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 either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

XI. STATEMENT OF INDICATIONS FOR INTENDED USE

510(k) Number (if known): K053641

Device Name:

Proton Therapy System.

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.

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

Concurrence of CDRH, Office of Device Evaluations (ODE)

Prescription Use ✓ OR Over-the-Counter Use

(Per 21 C.F.R. 801.109)
(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053641