JUL 1 2 2001

CONFIDENTIAL
K983024

## 510(k) SUMMARY

## Ion Beam Applications S.A.

### Applicant

Ion Beam Applications S.A.
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### Classification Name

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

### Predicate Devices

The PTS is substantially equivalent to the previously cleared Loma Linda University Medical Center ("Loma Linda") Proton Beam Therapy device (K872369) and the Harvard University Cyclotron Laboratory Proton Beam Therapy device, a pre-1976 device. The PTS 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 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**

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 is substantially equivalent to both the Loma Linda (K872369) and the 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 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. 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.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2001

Ion Beam Applications
% John B. Reiss, Ph.D., J.D.
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Re: K983024
Proton Therapy System
Dated: April 13, 2001
Received: April 16, 2001
Regulatory Class: II
21 CFR 892.5050/Procode: 90 LHN

Dear Dr. Reiss:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.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 (s)

## XI. STATEMENT OF INDICATIONS FOR INTENDED USE

510(k) Number (if known): K983024



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)

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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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K983024