APR 1 1 2006

510(K) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS

The following is based on the format of 21CFR807.92 Proton Therapy System – Proteus 235 Device modification – K060695..[to be completed by FDA]

Applicant

Ion Beam Applications S.A.
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Belgium

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Contact person and agent for Ion Beam Applications S.A.

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Classification Name

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

Predicate Device

PROTON THERAPY SYSTEM (K983024) and IBA PROTON THERAPY SYSTEM-PROTEUS 235 (K053641)

Description of the device modifications K060695

The device has been modified to introduce two additional treatment modes: the Single scattering and the Uniform scanning

1) The *single scattering* technique is a technique dedicated to the irradiation of fields smaller than seven centimeters in diameter. S*ingle scattering* decreases the amount of scattering in the nozzle compared to *double scattering* and lead to better lateral penumbra.

2) *Uniform scanning* is an active technique for spreading beam in a transversal direction. The incoming narrow beam, whose size is a significant fraction of the field to be treated, is moved by magnetic scanning so as to yield a flat field. The beam is deviated in x and y directions by two magnets, making the beam travel along a saw-tooth pattern with rounded corners. A patient specific aperture and bolus need therefore to be used just as in double scattering mode. A Uniform Scanning session is composed of several mini-irradiations that are used to build a Spread Out Bragg Peak within the treatment volume that is divided in a stack of layers, each of them corresponding to one penetration depth.

Intended 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.

Summary of technological characteristics

The substantial equivalence comparison chart provides a comparison of the technological characteristics to those of the predicate device. This chart is located in Appendix 6 of the submission.

IBA K060675

Exhibit 6 - Substantial Equivalence Comparison

	IBA Proton Therapy System including the Device Modifications implementing the Uniform Scanning new beam delivery modality	IBA Proton Therapy System including the Device Modifications implementing the Single scattering new beam delivery modality	IBA Proton Therapy System (K983024) for the legally marketed (unmodified) device
Intended Use	No Change	No Change	Treatment of patients with localized tumors and other conditions susceptible to treatment by radiation
Accelerator	No Change	No Change	Isochronous cyclotron
Particle	No Change	No Change	Proton
Proton Source	No Change	No Change	Hot cathode PIG ion source
Accelerator Parameters	No Change	No Change	Constant in time
Variable Energy	No change	No change	Yes (70-230 MeV), with Energy Selection System's Degrader
Maximum Energy	No Change	No Change	230 MeV
Injection Energy	No Change	No Change	N/A
Cycle Time	No Change	No Change	Constant in time
Beam Transport and Switching System	No Change	No Change	Beampipe through quadrupole and dipole magnet bore

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IBA K061695

	IBA Proton Therapy System including the Device Modifications implementing the Uniform Scanning new beam delivery modality	IBA Proton Therapy System including the Device Modifications implementing the Single scattering new beam delivery modality	IBA Proton Therapy System (K983024) for the legally marketed (unmodified) device
Beam Transport Magnets	No Change	No Change	Bending and focusing
Treatment Stations	No Change	No Change	Isocentric/Rotatable
Nozzles	Beam Scattering Uniform Beam Scanning	Beam Scattering	Beam Scattering
Beam Range in Patient (Tissue Depth)	3.5 cm to 32 cm for 40x30cm field	3.5 cm to 20 cm for Maximum field size 6 cm diameter field	5 cm to 28 cm for Φ 10 cm field 5 cm to 24 cm for Φ 20 cm field
Collimator	No Change	No Change	Yes
Range Verifier	No Change	No Change	Yes
Control and Safety System	No Change	No Change	• Hardwired Interlock System • Software controls accelerator and beam operation including beam transport and delivery, verifies patient ID, sets operational parameters, monitors systems, and provides alerts regarding excessive parameters

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IBA

K060695

	IBA Proton Therapy System including the Device Modifications implementing the Uniform Scanning new beam delivery modality	IBA Proton Therapy System including the Device Modifications implementing the Single scattering new beam delivery modality	IBA Proton Therapy System (K983024) for the legally marketed (unmodified) device
Mechanical Beam Stops	No Change	No Change	Yes
Beam Intensities	No Change	No Change	Hardware-limited at 300 nA continuous (1.1×10^{14} protons/min). ESS further limits maximum possible patient dose rate.
Shielding	No Change	No Change	Steel and Concrete around accelerator, transport, and treatment areas
Treatment Rooms	No Change	No Change	3 (one with fixed horizontal beam and two with isocentric gantry)
Patient Positioner	No Change	No Change	Yes

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1 2006

ION Beam Applications S.A.
% John B. Reiss, Ph.D., J.D.
Official Correspondent
Saul, Ewing, Attorneys at Law
Centre Square West
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PHILADELPHIA PA 19102-2186

Re: K060695
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: LHN
Dated: March 15, 2006
Received: March 16, 2006

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 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

STATEMENT OF INDICATIONS FOR INTENDED USE

510(k) Number (if known): K060695

Device Name:

IBA 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.

(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 K060695