DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 9, 2016

Ion Beam Application S.A.
% Mr. Bruce Armon
Partner
Saul Ewing LLP
Center Square West, 1500 Market Street, 38th Floor
PHILADELPHIA PA 19102-2186

Re: K152224
Trade/Device Name: Proton Therapy System - Proteus 235 (Proteus One, Proteus Plus, Proteus TK2)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: July 4, 2016
Received: July 8, 2016

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152224

Device Name
Proton Therapy System - Proteus 235 (Proteus One, Proteus Plus, Proteus TK2)

Indications for Use *(Describe)*
"The Proton Therapy System - Proteus 235 (brand names: Proteus Plus and Proteus ONE) 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."

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Ion Beam Applications S.A.

24 June 2016

Applicant

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Classification Name

Medical Charged-Particle Radiation Therapy Systems. (21 C.F.R. §892.5050, Product Code LHN)

Trade Name: Proton Therapy System - Proteus 235, Proteus One, Proteus Plus, Proteus TK2.

Common Name: Proton Therapy System

Predicate Device

The IBA Proton Therapy System – Proteus 235 (PTS) with the addition of the IBA Compact Beam Production System is substantially equivalent to the previously cleared IBA Proton Therapy System (K132919) and to the S-250 Proton Beam Radiation Therapy system (K120676) from Mevion Medical Systems that includes a super conducting synchrocyclotron accelerator. The current PTS and its predicate devices have the same intended use and principles of operation, and are substantially equivalent in terms of technological characteristics.

Indication for Use

The intended use of the product (wth the addition of the IBA Compact Beam Production Systems (CBPS) is not changed in respect to the previously cleared intended use (including no change in labelling that would affect it):

"The Proton Therapy System - Proteus 235 (brand names: Proteus Plus and Proteus ONE) 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."

Pre-market notification description

The change introduced in the IBA Proton Therapy System - Proteus 235 and described in this filing is the introduction of an optionally new IBA Compact Beam Production System (CBPS). Compact Beam Production System (CBPS) feature consists of the introduction, as an option, of a SuperConducting Synchro-Cyclotron (S2C2), offering a compact and more affordable alternative to the isochronous cyclotron. Both synchro-cyclotron and isochronous cyclotron are dedicated to the generation of high energy protons for protontherapy. This is accompanied by an adaptation of the beam delivery equipment, which directs the proton beam to the patient's treatment site, to process the beam produced by the S2C2.

Description of the device modification

This PTS corresponds to the previously cleared IBA Proton Therapy System (K132919) with the addition of IBA Compact Beam Production System (CBPS) based on a Superconducting Synchro-cyclotron (S2C2), which produces and delivers a proton beam for the treatment of patients.

A Proteus 235 Proton Therapy System (PTS) includes one proton accelerator for the production of the beam which can be shared between several treatment rooms in the Proteus Plus configurations and directed towards one only room in the Proteus One configurations. With the actual change, the accelerator can be either the isochronous cyclotron (C230) as in the previously cleared IBA PTS, or a Superconducting Synchro-Cyclotron (S2C2). As before, the PTS can be equipped with treatment rooms of several types according to the range of beam incidences they offer: e.g. a fixed beam treatment room or a gantry treatment room. These rooms are connected to the beam line transporting the protons produced by the accelerator (C230 or S2C2).

This change has no impact on:

- The intended use(including no changes in labelling that would affect it);
- The fundamental scientific technology of the Proteus 235 including operating principles and mechanism of action;
- The product's clinical efficacy.

Technological Characteristics of the modified device

The following table gives a high level overview of the main characteristics of the IBA Superconducting Synchro-cyclotron (S2C2), compared to the predicate conventional IBA isochronous cyclotron (C230), as in the previously cleared PTS, and the predicate synchro-cyclotron from Mevion Medical Systems already used in Proton Therapy.

Characteristic	IBA Isochronous cyclotron C230	IBA Superconducting synchrocyclotron S2C2	Mevion Medical Systems synchrocyclotron S-250
Accelerator	230 MeV isochronous cyclotron	230 MeV superconducting synchrocyclotron	250 MeV superconducting synchrocyclotron
Particle	Proton	Proton	Proton
Energy range	up to 230 MeV with energy selection system	up to 230 MeV with energy selection system	Up to 250 MeV
Ion Source	Hot cathode PIG ion source	Cold cathode PIG source	Cold cathode PIG source
Type of coils	Resistive coils	Superconducting coils	Superconducting coils
Volume (m^3)	~30	~10	3-5
Weight (tons)	~230	~42	~20
Estimated Electrical power consumption	2258 MWh/year	358 MWh/year	100 MWh/year
Cooling method	Chilled water	Chilled water and Gifford-Mc Mahon cryocoolers	Gifford-Mc Mahon cryocoolers

Table 1: Overview of the main characteristics of the synchro-cyclotron versus the IBA Isochronous cyclotron and the Mevion synchrocyclotron

The Proteus 235 with the CBPS feature has the same intended use and indications, principles of operation, and technological characteristics as IBA Proton Therapy System (K132919) and to the S-250 Proton Beam Radiation Therapy system (K120676) from the Mevion Medical Systems for the synchrocyclotron accelerator.

Summary of Performance testing

Testing has been performed at the system and sub-system level and demonstrated that the IBA Proton Therapy System - Proteus 235 with the CBPS new feature is substantially equivalent to the predicate device. Thus, this device is as safe, as effective and performs as well as the predicate device. From those testing, the following results have been obtained:

Characteristic	IBA Proteus Compact Gantry Beam Line with Superconducting synchrocyclotron (CBPS) (K152224)	IBA Proteus Compact Gantry Beam Line with C230 cyclotron (K 132919)
Maximum Beam Range in Patient (Tissue depth)	> or = 32 cm	> or = 32 cm
Field Size	24 cm x 20 cm	24 cm x 20 cm
Beam Distal Fall Off	≤0.25 g/cm2 above the physical limit	≤0.25 g/cm2 above the physical limit
Spot Size	≤ 15 mm on the range of energies	≤ 15 mm on the range of energies
Spot Position Accuracy	≤ 15 % of beam sigma or < to 1.5 mm	≤ 15 % of beam sigma or < to 1.5 mm
Irradiation Time	≤2 minutes for delivering 2Gy to 1L volume (10 x 10 x 10 cm3)	≤2 minutes for delivering 2Gy to 1L volume (10 x 10 x 10 cm3)
Effective SAD	≥ 2m	≥ 2m

Table 2. Overview of the clinical beam performance characteristics of the IBA Proton Therapy System using a cyclotron versus synchrocyclotron

Conclusion

The verification and validation activities ensure that the device is as safe, as effective, and performs as well as the predicate device.