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,

[Signature]

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

Enclosure
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)

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

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510(k) SUMMARY

Ion Beam Applications S.A.

24 June 2016

Applicant

Ion Beam Applications S.A.
Chemin du Cyclotron, 3
B-1348 Louvain-la-Neuve
Belgium
Attention: Mrs. Anne-Sophie Grell
Phone: 32-10-47-58-16
Facsimile: 32-10-47-58-10
E-mail: anne-sophie.grell@iba-group.com

Contact and Agent for Ion Beam Applications S.A.

Bruce D. Armon
Saul Ewing LLP
1500 Market Street
Centre Square West – 38th Floor
Philadelphia, PA 19102
Phone: (215) 972-7124
Facsimile: (215) 972-1906
E-mail: barmon@saul.com
**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 superconducting 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 (with 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 synchrocyclotron 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.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>IBA Isochronous cyclotron C230</th>
<th>IBA Superconducting synchrocyclotron S2C2</th>
<th>Mevion Medical Systems synchrocyclotron S-250</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accelerator</td>
<td>230 MeV isochronous cyclotron</td>
<td>230 MeV superconducting synchrocyclotron</td>
<td>250 MeV superconducting synchrocyclotron</td>
</tr>
<tr>
<td>Particle</td>
<td>Proton</td>
<td>Proton</td>
<td>Proton</td>
</tr>
<tr>
<td>Energy range</td>
<td>up to 230 MeV with energy selection system</td>
<td>up to 230 MeV with energy selection system</td>
<td>Up to 250 MeV</td>
</tr>
<tr>
<td>Ion Source</td>
<td>Hot cathode PIG ion source</td>
<td>Cold cathode PIG source</td>
<td>Cold cathode PIG source</td>
</tr>
<tr>
<td>Type of coils</td>
<td>Resistive coils</td>
<td>Superconducting coils</td>
<td>Superconducting coils</td>
</tr>
<tr>
<td>Volume (m³)</td>
<td>~30</td>
<td>~10</td>
<td>3-5</td>
</tr>
<tr>
<td>Weight (tons)</td>
<td>~230</td>
<td>~42</td>
<td>~20</td>
</tr>
<tr>
<td>Estimated Electrical power consumption</td>
<td>2258 MWh/year</td>
<td>358 MWh/year</td>
<td>100 MWh/year</td>
</tr>
<tr>
<td>Cooling method</td>
<td>Chilled water</td>
<td>Chilled water and Gifford-Mc Mahon cryocooolers</td>
<td>Gifford-Mc Mahon cryocoollers</td>
</tr>
</tbody>
</table>

**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:

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>IBA Proteus Compact Gantry Beam Line with Superconducting synchrocyclotron (CBPS) (K152224)</th>
<th>IBA Proteus Compact Gantry Beam Line with C230 cyclotron (K 132919)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Beam Range in Patient (Tissue depth)</td>
<td>≥ 0 cm or ≥ 32 cm</td>
<td>≥ 0 cm or ≥ 32 cm</td>
</tr>
<tr>
<td>Field Size</td>
<td>24 cm x 20 cm</td>
<td>24 cm x 20 cm</td>
</tr>
<tr>
<td>Beam Distal Fall Off</td>
<td>≤0.25 g/cm² above the physical limit</td>
<td>≤0.25 g/cm² above the physical limit</td>
</tr>
<tr>
<td>Spot Size</td>
<td>≤ 15 mm on the range of energies</td>
<td>≤ 15 mm on the range of energies</td>
</tr>
<tr>
<td>Spot Position Accuracy</td>
<td>≤ 15 % of beam sigma or &lt; to 1.5 mm</td>
<td>≤ 15 % of beam sigma or &lt; to 1.5 mm</td>
</tr>
<tr>
<td>Irradiation Time</td>
<td>≤2 minutes for delivering 2Gy to 1L volume (10 x 10 x 10 cm³)</td>
<td>≤2 minutes for delivering 2Gy to 1L volume (10 x 10 x 10 cm³)</td>
</tr>
<tr>
<td>Effective SAD</td>
<td>≥ 2m</td>
<td>≥ 2m</td>
</tr>
</tbody>
</table>

**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.