DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 17, 2017

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

Re: K163500
Trade/Device Name: IBA Proton Therapy System- Proteus 235 (Proteus One, Proteus Plus, Proteus TK2, Proteus Class)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: LHN
Dated: December 9, 2016
Received: December 19, 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,

Michael D. O'Hara For

Robert A. 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)*

K163500

Device Name

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

Indications for Use *(Describe)*

The IBA Proton Therapy System (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. 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

In accordance with 21 CFR 807.92 the following summary of information is provided:

June 28th, 2017

1. 510(k) Holder

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2. Device

Trade Name:	Proton Therapy System - Proteus 235, Proteus One, Proteus Plus, Proteus TK2, Proteus Class.
Common Name:	Proton Therapy System
Classification Name:	Medical Charged-Particle Radiation Therapy Systems
Classification regulation:	21 CFR § 892.5050
Product Code:	LHN

3. Predicate Device

The IBA Proton Therapy System – Proteus 235 (PTS) with the addition of the IBA wireless hand-pendant System is substantially equivalent to the previously cleared IBA Proton Therapy System (K152224). The current PTS and its Primary predicate device have the same intended use and principles of operation, and are substantially equivalent. This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

4. Device Description

IBA Proton Therapy System – Proteus 235 (PTS) is a proton beam irradiation system. 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 three primary components: (1) the beam management equipment, which includes a cyclotron, transport and delivery system to direct the proton beam to the patient's treatment location; (2) the position management equipment that allows bringing the patient and the proton beam in the adequate position for treatment and verifying the patient position; and (3) the treatment control system which controls the parameters of the proton beam treatment.

The scope of the current 510(k) premarket notification is to add a new version of the hand-pendant, which uses wireless and touch screen technologies to move equipment in the treatment room to the cleared IBA Proteus 235.

5. Intended Use

The intended use of the product with the addition of the IBA wireless hand-pendant System 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."

6. Summary of Technological Characteristics compared to the predicate device

The IBA Proton Therapy System – Proteus 235 (PTS) with the addition of the IBA wireless hand-pendant System and the previously cleared IBA Proton Therapy System – Proteus 235 (K152224) are identical in terms of intended use, principles of operation, energy source delivered to the patient and clinical performance. The difference between both systems is the introduction of the wireless and touch screen technologies in the patient positioning management system.

The following table gives a high level overview of the main changes of the IBA wireless hand-pendant compared to the predicate IBA wired hand-pendant.

Characteristic	Predicate device: Proteus 235 with wired hand-pendant (K152224)	Proteus 235 with wireless hand-pendant
Hand-pendant weight	< 700 g	< 250 g
Hand-pendant volume	< 3500 cm^3	< 400 cm^3
Hand-pendant communication link	Wired communication link	Wireless communication link
User interface	Passive display screen Buttons for movement and selection	Touch screen

Table 1: Overview of the main changes of the new hand-pendant

The positioning management system remains iso-functional and the moving equipment control is not modified.

7. Summary of Non-Clinical Tests

IBA Proton Therapy System - Proteus 235 with wireless hand-pendant System was tested to and complies with applicable voluntary standards detailed in this premarket submission.

Ion Beam Applications conducted non-clinical tests at the system and sub-system levels. These tests assess the performance of Proteus 235 with wireless hand-pendant System. The following tests have been provided in support of the substantial equivalence determination.

- Electrical safety was evaluated and electromagnetic compatibility testing was performed with the wireless hand-pendant system. The wireless hand-pendant was found to comply with recognized standards for electrical safety and electromagnetic compatibility.
- Human factor validation testing was conducted to assess usability of the system. Users conducted a series of movements under real and simulated conditions.
- Software tests verifying the software performs as intended.
- Hardware verification and reliability testing ensuring the wireless hand-pendant hardware performs as intended.
- Performance testing was conducted to ensure the product meets intended performance design inputs during normal conditions of use. The performance testing includes wireless coexistence testing in accordance with the FDA guidance document Radio Frequency Wireless Technology in Medical Devices (August 14,2013), latency measurement, operating distance testing, and FCC radio Frequency testing according to 47 CFR Part 15 (§15.247).

Non-clinical testing was performed to confirm that the changes in IBA Proton Therapy System - Proteus 235 with wireless hand-pendant System met design requirements and did not affect the safety or effectiveness of the product.

8. Summary of Clinical Tests

The subject of this premarket submission, IBA Proton Therapy System – Proteus 235 (PTS) with the addition of the IBA wireless hand-pendant System, did not require clinical studies to support substantial equivalence.

9. Conclusion

The verification and validation activities ensure that the IBA Proton Therapy System – Proteus 235 (PTS) with the addition of the IBA wireless hand-pendant System is as safe, as effective, and performance is substantially equivalent to the predicate device.