September 27, 2019

ProTom International Holding Corporation
% Mr. Jonathan Kahan
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
WASHINGTON DC 20004

Re: K191521
Trade/Device Name: Radiance 330™ Proton Beam Therapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: LHN
Dated: August 27, 2019
Received: August 27, 2019

Dear Mr. Kahan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K191521

Device Name
Radiance 330™ Proton Beam Therapy System

Indications for Use *(Describe)*
The ProTom Radiance 330 is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other condition susceptible to treatment by radiation.

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 K191521

Radiance 330® Proton Therapy Device

Submitter:

ProTom International Holding Corporation

500 Edgewater Place, Suite 522
Wakefield, MA 01880
Phone: (781) 245-3964
Facsimile: None

Contact Person: Stephen L. Spotts
Chief Executive Officer
Phone: 214-538-7020

Date Prepared: June 26, 2019

Name of Device:

Radiance 330™ Proton Beam Therapy System

Common or Usual Name:

Proton Beam Therapy Device

Classification Name:

System, Radiation Therapy, Charged-Particle, Medical

Regulatory Class:

Class II

Product Code:

LHN

Predicate Devices:

ProTom International, Inc. Radiance 330® Proton Therapy System (K134052)

Device Description:

The ProTom Radiance 330® is a medical device designed to produce and deliver a proton beam for the treatment of patients with solid tumors or other diseases susceptible for treatment by radiation. The device includes a method for delivering an accelerated proton beam to the treatment station. The device also includes equipment to position the patient and direct the beam angle.

The system is comprised of six main subsystems that function in tandem to generate the desired dose level and distribution at the target site.

1. Beam Production Subsystem. Produces a proton beam at the desired energy level
2. Beam Transport Subsystem. Transports the beam from the Beam Production Subsystem to the Beam Delivery Subsystem
3. Beam Delivery Subsystem. Monitors and steers the beam to the desired treatment location
4. Gantry Subsystem. Mechanically orients the Beam Transport and Beam Delivery Subsystems; providing a means of patient x-ray registration
5. Patient Positioning Subsystem. Mechanically orients the patient; provide a separate and means of patient x-ray registration
6. Control Subsystem. Synchronizes the various subsystem actions and connects with hospital oncology information systems

Intended Use / Indications for Use:

The ProTom Radiance 330® 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 and Comparison to the Predicate:

At a high level, the ProTom Radiance 330® and the cleared ProTom Radiance 330® (K134052), to which it is a modification, are based on the following same technological elements. The systems have the same primary components and achieve radiation therapy in the same way, namely by accelerating protons for delivery through a nozzle to the patient. The Radiance 330® Proton Therapy System and predicate are designed to deliver a prescribed dose of proton radiation treatment to patients with solid tumors or other diseases susceptible to radiation. The current system in a single room application. Minor differences in the systems accommodate preferences of the clinical site installation including differences in certain suppliers and interfaces with existing hospital systems.

Table 1: Substantial Equivalence Table

Comparison Item	ProTom Radiance 330®	ProTom Radiance 330
510(k) Number	Subject of this application	K134052
Intended Use/ Indications for Use	The Radiance 330 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.	Same
Accelerator	Synchrotron	Same
Particle	Protons	Same
Accelerator Intensity/Time Parameters	Variable in time	Same

Comparison Item	ProTom Radiance 330®	ProTom Radiance 330
Variable Energy	Yes; 70-250 MeV	Same
Cycle Time	Variable	Same
Beam Transport and Switching System	Yes	Same
Beam Transport Magnets	Bending and focusing magnets	Same
Nozzles	Pencil Beam Scanning	Same
Beam Range in Patient (Tissue Depth)	3 cm to 38 cm clinical use	Same
Collimator	Optional	Same
Range Verifier	Optional	Same
Control and Safety System	Software controls accelerator, beam transport and delivery, sets operational parameters, monitors systems and provides alerts regarding error conditions.	Same other than integrated into fewer subsystem controls
Safety System	Distributed Safety implementation	Same
Mechanical Beam Stops	Yes	Same
Beam Intensities	Continuously variable over range up to 1E10 protons per cycle time.	Same .
Shielding	Steel and Concrete	Same
Beam Lines	Yes	Same
Treatment Room(s)	Fixed beam orientation and rotating gantry	Same
Patient Positioner	Yes – floor mounted (different supplier)	Yes – floor mounted
Imaging for positioning	Yes – couch mounted CBCT	Yes – ceiling mounted CBCT

Performance Data:

Each individual subsystem of the device was verified and validated, and full system verification and validation was also performed. Specifically, device verification and validation testing was performed on gantry acceleration and de-acceleration, beam delivery rate dosimetry, radiation shielding, gating, geometric accuracy, image quality, image dose, accuracy of CT number and image, X-ray imaging device registration accuracy. Testing was also conducted to evaluate human factors considerations. Device software was verified and validated.

Basic Safety and Essential Performance of the device covered the intended use environment to fulfil the complete necessary workflow to deliver pencil beam patterns, control of all motion components, measure delivery dose, respond to interlocks and safety signals, and log data and errors. Product safety and essential performance testing was conducted based upon IEC 60601-1, IEC 6006-1-2, IEC 60601-2-64, IEC 60601-2-68, and IEC 60825-1.

In all instances, the Radiance 330® Proton Therapy Device functioned as intended and was substantially equivalent in terms of performance and safety in comparison to the predicate.

Conclusions:

The Radiance 330® is as safe and effective as the cleared Radiance 330 Proton Beam Therapy System to which it is a modification. The Radiance 330® has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Radiance 330® Proton Beam Therapy System and its predicate device do not raise different questions of safety or effectiveness. Performance data demonstrate that the Radiance 330® is as safe and effective as the cleared Radiance 330®. Thus, the Radiance 330 is substantially equivalent to its predicate.