Hitachi Ltd.
℅ Mr. Jonathan Kahan
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
WASHINGTON DC 20004

September 13, 2019

Re: K191801
Trade/Device Name: PROBEAT-CR 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: July 3, 2019
Received: July 3, 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,

For

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191801

Device Name
PROBEAT-CR Proton Beam Therapy System

Indications for Use *(Describe)*
The PROBEAT-CR 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY K191801

PROBEAT-CR Proton Beam Therapy Device

Submitter Name, Address, Telephone Number, Contact Person and Date Prepared

Hitachi Ltd., Healthcare Hitachi Works
3-1-1 Saiwai-cho, Hitachi-shi
Ibaraki-ken, 317-8511, Japan
Telephone: +81 (294) 55-5900
Facsimile: +81 (294) 55-9946

Contact Person: Tomoyuki Seino

Date Prepared: July 3, 2019

Name of Device:

PROBEAT-CR 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:

Hitachi Ltd. PROBEAT-V (K151132)
Hitachi Ltd. PROBEAT-V (K152592)

Device Description

The PROBEAT-CR is a proton beam irradiation system, which provides a therapeutic proton beam for clinical treatment. It is designed to deliver a proton beam with the prescribed dose, dose distribution and directed to the prescribed patient treatment site. The PROBEAT-CR is a modification to the cleared PROBEAT-V system, for installation at a different clinical site.

Intended Use / Indications for Use

The PROBEAT-CR 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 PROBEAT-CR has two main subsystems: (1) equipment necessary to generate the proton beam and direct it to the beam delivery system for patient treatment, and (2) a beam delivery system whose primary responsibility is to ensure that the desired prescription parameters are properly delivered. The PROBEAT-CR comprises the following components and subsystems:

- Beam production system
  - Accelerator system (LINAC, Synchrotron).
  - Beam transport system (Low/High Energy Beam Transport systems).
- Beam delivery system in 4 separate treatment rooms. Each of 3 rooms will have a rotating gantry and 1 room will have a fixed beam.
  - Gantry Room
    - Scanning Nozzle
    - Rotating Gantry
    - Patient Positioning System
    - Orthogonal X-ray system
    - Cone Beam CT
  - Fixed Beam Room
    - Patient Positioning System
    - Orthogonal X-ray system
- Treatment Control and Safety System

The PROBEAT-CR is a modification to the cleared PROBEAT-V systems for use at a difference clinical facility. The system comprises the same components and subsystems as outlined above, with minor differences in design as summarized in the following table.

Table 1: Substantial Equivalence Table

Comparison Item	Hitachi PROBEAT-CR	Hitachi PROBEAT-V	Hitachi PROBEAT-V
510(k) Number	- Pending -	K151132	K152592
Intended Use/ Indications for Use	The PROBEAT-CR 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 PROBEAT-V 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 PROBEAT-V 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.
Accelerator	Synchrotron	Synchrotron	Synchrotron

Comparison Item	Hitachi PROBEAT-CR	Hitachi PROBEAT-V	Hitachi PROBEAT-V
Particle	Protons	Protons	Protons
Variable energy	70-230 MeV	70-230 MeV	70-230 MeV
Nozzles	Discrete Spot Scanning	Discrete Spot Scanning	Discrete Spot Scanning
Support for patient positioning	• Cone Beam CT • Conventional x-ray system • A computer assisted patient position system	• Conventional x-ray system • A computer assisted patient position system	• Cone Beam CT • Conventional x-ray system • A computer assisted patient position system
Treatment rooms	3 rotating gantry rooms and 1 fixed beam room (Maximum 5 total)	4 rotating gantry rooms and 1 fixed beam room (Maximum 5 total)	2 rotating gantry rooms and 1 fixed beam room (Maximum 5 total)
Gantry rotating angle	360 degrees (-180 – 180 degrees)	190 degrees (-5 – 185 degrees)	190 degrees (-5 – 185 degrees)

Performance Data

The company performed testing, as follows:

- The mechanical performance of the rotating gantry and patient couch
- Beam performance testing to evaluate beam dose shape and beam dose
- Safety interface testing to evaluate beam stop control, dose monitor, area safety, and mechanical interlocks.

Further, electrical safety and electromagnetic compatibility testing was also performed in accordance with IEC 60601-1 and IEC 60601-1-2.

In all instances, the PROBEAT-CR functioned as intended and met its specifications. Testing demonstrated substantial equivalence to the predicates.

Conclusions

The PROBEAT-CR has the same intended use and indications for use, as well as substantially similar principles of operation and technological characteristics, as compared to Hitachi's cleared PROBEAT-V (K151132, K152592). Each of the systems comprises the same components of the beam production and beam delivery subsystems. The minor differences between the PROBEAT-CR that is the subject of this submission and the cleared PROBEAT-V do not raise different questions of safety or effectiveness. Performance data demonstrate that the PROBEAT-CR is as safe and effective as the cleared PROBEAT-V systems Thus, the PROBEAT-CR is substantially equivalent to its predicates.