Hitachi, Ltd. Radiation Oncology Systems, Kashiwanoha
% Lina Kontos
Partner
Hogan Lovells US LLP
555 THIRTEENTH STREET, NW
WASHINGTON, DISTRICT of COLUMBIA 20004

Re: K232032
Trade/Device Name: Probeat-fr
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: LHN
Dated: December 18, 2023
Received: December 19, 2023

Dear Ms. Lina Kontos:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Xin He -S Digitally signed by Xin He -S Date: 2024.01.12 09:02:46 -05'00' for

Lora Weidner
Assistant Director
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232032

Device Name

PROBEAT-FR

Indications for Use *(Describe)*

The PROBEAT-FR 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)*

☒ 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
Hitachi Ltd.'s PROBEAT-FR Proton Beam Therapy Device

Submitter

Hitachi, Ltd. Radiation Oncology Systems, Kashiwanoha
226-44-141-1, Wakashiba, Kashiwa-shi, Chiba-ken, 277-0871, Japan
Contact Person: Tomoko Irisa

Date Prepared: January 9, 2024

Name of Device:

PROBEAT-FR 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, Classification Regulation:

LHN, 21 C.F.R. § 892.5050

Predicate Device

Hitachi Ltd., Healthcare Radiation Oncology Systems, Kashiwa, PROBEAT-CR Proton Beam Therapy Device (K201042)

Device Description

The PROBEAT-FR 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.

Intended Use / Indications for Use

Hitachi's PROBEAT-FR 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

Consistent with the cleared PROBEAT-CR systems, the PROBEAT-FR 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 4 rooms will have a rotating gantry.
  - Gantry Room
    - Scanning Nozzle
    - Rotating Gantry
    - Patient Positioning System (Patient Couch)
      - X-ray Imaging System
      - Cone Beam CT
      - In-Room CT (Optional)
      - Positioning Image Analysis System
- Treatment Control and Safety System

The PROBEAT-FR is a modification to the cleared PROBEAT-CR system to include a somewhat larger gantry, moving snout and also a rapid mode for the CBCT. The system comprises the same components and subsystems as outlined above, with minor differences in design as summarized in the table below.

Comparison Item	Hitachi PROBEAT-FR	Hitachi PROBEAT-CR
510(k) Number	K232032	K201042
Intended Use/ Indications for Use	The PROBEAT-FR 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-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.
Accelerator	Synchrotron	Synchrotron
Particle	Protons	Protons
Variable energy	70-230 MeV	70-230 MeV
Nozzles	Discrete Spot Scanning Moving snout	Discrete Spot Scanning

Comparison Item	Hitachi PROBEAT-FR	Hitachi PROBEAT-CR
Support for patient positioning	Gantry built-in type Cone Beam CT is used to verify patient positioning. Rapid mode can be selected. A conventional x-ray system can be also equipped in the same treatment room. A computer assisted patient position system (PIAS) is available for use.	Gantry built-in type Cone Beam CT is used to verify patient positioning. A conventional x-ray system can be also equipped in the same treatment room. A computer assisted patient position system (PIAS) is available for use
Treatment rooms	Typically 4 rotating gantry rooms.	Typically 3 rotating gantry rooms and 1 fixed beam room.
Gantry and rotating angle	Large gantry 360 degrees (0−180 degrees, 180-359 degrees)	Compact gantry 360 degrees (-180 – 180 degrees)
Patient Positioner	Rotating gantry room. a. Patient Couch Swing type Robotic Patient Positioning System with 6 degrees of freedom. Isocentric rotating angle of the couch is ± 95 degrees for standard base and extension configuration. b. Laser Alignment System	Rotating gantry room and fixed room. a. Patient Couch Swing type Robotic Patient Positioning System with 6 degrees of freedom. Isocentric rotating angle of the couch is ±degrees for standard base and extension configuration. With the optional couch top extension, isocentric rotating angle can be extended to ±90 degrees for short base and overlay configuration, with a ±5 degree movement range for the rolling and pitching angles. b. Laser Alignment System
Use of Image Gating System Software	Real Time Image Gating System software is incorporated into the system.	Real Time Image Gating System software is incorporated into the system.

Performance Data

The company performed testing, as follows:

- The mechanical performance of the rotating gantry, patient couch and moving snout.
- Beam performance testing to evaluate beam dose shape and beam dose
- Real time image gated particle therapy software test
- Imaging guidance function of CBCT and PIAS
- Safety interlock testing to evaluate beam stop control, dose monitor, area safety, mechanical and RGPT interlocks.

- Comprehensive test depending on treatment workflow test.

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-FR functioned as intended and met its specifications. Testing demonstrated substantial equivalence to the predicates.

Conclusions

The PROBEAT-FR is as safe and effective as the predicate PROBEAT-CR System. PROBEAT-FR has the same intended uses and indications, similar technological characteristics, and principles of operation as its predicate device. The minor differences between the PROBEAT-FR that is the subject of this submission and the cleared PROBEAT-CR do not raise different questions of safety or effectiveness. Performance data demonstrate that the PROBEAT-FR is as safe and effective as the cleared PROBEAT-CR system. Thus, the PROBEAT-FR is substantially equivalent to its predicates.