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

July 13, 2020

Re: K201042
Trade/Device Name: PROBEAT-CR
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: LHN
Dated: April 20, 2020
Received: April 20, 2020

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)*

K201042

Device Name

PROBEAT-CR

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)*

☒ 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-CR Proton Beam Therapy Device

Submitter K201042

Hitachi Ltd., Healthcare Radiation Oncology Systems, Kashiwa
2-1 Shintoyofuta, Kashiwa-shi
Tiba-ken, 277-0804, Japan
Telephone: +81 (4) 7131-4280
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Contact Person: Tomoyuki Seino

Date Prepared: April 20, 2020

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., Healthcare Hitachi Works, PROBEAT-CR Proton Beam Therapy Device (K191801)

Reference Devices

Hitachi Ltd., Healthcare Hitachi Works, Real Time Image Gating System for Proton Beam Therapy Systems (K171049)

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.

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 subject PROBEAT-CR is a modification to the cleared PROBEAT-CR to include the incorporation of the previously cleared Real Time Image Gating System for Proton Beam Therapy Systems (“RGS” or “RGPT”) (K171049) for tracking implanted fiducials to gate the delivery of the proton beam, and the addition of an optional patient couch top extension as an accessory to allow for different patient positioning configurations.

A table comparing the key features of the subject and predicate devices is provided below.

Performance Data

The following testing was performed to validate the modifications to the device:

- Design verification and validation testing for the addition of the optional top couch extension
- Software verification and validation for the updated RGS (RGPT) software

Conclusions

The company's subject PROBEAT-CR is as safe and effective as the predicate PROBEAT-CR. The subject PROBEAT-CR has the same intended use and indications as the previously cleared PROBEAT-CR. In addition, the subject PROBEAT-CR has very similar technological characteristics and principles of operation as its predicate. Although there are minor differences between the PROBEAT-CR and the predicate, namely the incorporation of the cleared RGS (RGPT) software system and the addition of an optional patient couch top extension, those differences do not raise new questions of safety or efficacy. The performance testing demonstrates that the device is as safe and effective as the predicate. Thus, the PROBEAT-CR is substantially equivalent.

Substantial Equivalence Table

	Hitachi PROBEAT-CR (Subject Device)	**Hitachi PROBEAT-CR (K191801)**
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-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	Discrete Spot Scanning
Support for Patient Positioning	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.	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.

	Hitachi PROBEAT-CR (Subject Device)	Hitachi PROBEAT-CR (K191801)
Treatment Room	Typically 3 rotating gantry rooms and 1 fixed beam room (Maximum 5 total). <Note>All rooms are dedicated to the DSSS	Typically 3 rotating gantry rooms and 1 fixed beam room (Maximum 5 total). <Note>All rooms are dedicated to the DSSS
Gantry rotating angle	360 degrees (-180−180degrees)	360 degrees (-180−180degrees)
Patient Positioner	Rotating gantry room and fixed beam room, (a) Patient Couch Swing type Robotic Patient Positioning System with 6 Degrees of freedom Isocentric rotating angle of the couch is ±45 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	Rotating gantry room and fixed beam room, (a) Patient Couch Isocentric rotating angle of the couch is ±45 degrees for standard base and extension configuration. (b) Laser Alignment System
Patient Positions Supported	Head first-supine (“HFS”), head first-prone (“HFP”), feet first-supine (“FFS”), and feet first-prone (“FFP”)	Head first-supine (“HFS”)
Treatment Room	3 rotating gantry rooms and 1 fixed beam room (Maximum 5 total).	3 rotating gantry rooms and 1 fixed beam room (Maximum 5 total).
Use of Image Gating System Software	Real Time Image Gating System software is incorporated into the system.	System is compatible with Real Time Image Gating System software but the software is not incorporated.