June 11, 2026

Hitachi High-Tech, Corp. Kashiwanoha
℅ John Smith
Partner
Hogan Lovells US LLP
555 Thirteenth St., NW
Washington, District of Columbia 20004

Re: K260174
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: May 10, 2026
Received: May 11, 2026

Dear John Smith:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260174

Please provide the device trade name(s).

PROBEAT-CR

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY
Hitachi High-Tech, Corp.'s PROBEAT-CR Proton Beam Therapy Device

Submitter

Hitachi High-Tech, Corp. Kashiwanoha
226-44-141-1, Wakashiba, Kashiwa-shi, Chiba 277-0871, Japan

Contact Person: Takanari Kuriyama

Date Prepared: June 10, 2026

Name of Device:

PROBEAT-CR

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-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-CR system (K201042).

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

Consistent with the cleared PROBEAT-CR systems, 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
  - Gantry Room
    - Scanning Nozzle
    - Rotating Gantry
  - Patient Positioning System
  - X-ray Imaging System
  - Cone Beam CT
  - Positioning Image Analysis System
  - Real-time image gated proton therapy (RGPT)
- Treatment Control and Safety System

The PROBEAT-CR is a modification to the cleared PROBEAT-CR system. 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-CR	Hitachi PROBEAT-CR
510(k) Number	K260174	K201042
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-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 LINAC with Radio Frequency Quadrupole (RFQ).	Synchrotron LINAC with Drift tube and Radio Frequency Quadrupole (RFQ).
Particle	Protons	Protons
Variable energy	70-230 MeV	70-230 MeV
Support for patient positioning	Gantry built-in type Cone Beam CT is used to verify patient positioning.	Gantry built-in type Cone Beam CT is used to verify patient positioning.

Comparison Item	Hitachi PROBEAT-CR	Hitachi PROBEAT-CR
	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.	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	Rotating gantry room.	Rotating gantry rooms and a fixed beam room.
Gantry and rotating angle	Compact gantry 360 degrees	Compact gantry 360 degrees
Patient Positioner	Rotating gantry room. a. Patient Couch Patient Positioning System with 6 degrees of freedom. b. Laser Alignment System	Rotating gantry room. a. Patient Couch Patient Positioning System with 6 degrees of freedom. b. Laser Alignment System
Imager for patient positioning	CBCT + bowtie filter	CBCT
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.
Beam adjustment	Range shifters 1 mm, 2 mm, 3mm, 4 mm, 5 mm, 40mm, Extendable Extended Range Shifter	Range shifters 3 mm, 40mm
Treatment Management System Interface	Integrated Worklist Manager (WLM) and Interface Software for proton Therapy (IST) for external OIS connectivity	Interface Software for proton Therapy (IST)

Performance Data

The company performed testing, as follows:

- Beam performance testing to evaluate beam dose shape and beam dose
- Imaging guidance function of CBCT
- OIS interface and function of WLM 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-CR functioned as intended and met its specifications. Testing demonstrated substantial equivalence to the predicates.

Conclusions

The PROBEAT-CR is as safe and effective as the predicate PROBEAT-CR System. PROBEAT-CR has the same intended uses and indications, similar technological characteristics, and principles of operation as its predicate device. The minor differences between the PROBEAT-CR 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-CR is as safe and effective as the cleared PROBEAT-CR system. Thus, the PROBEAT-CR is substantially equivalent to its predicates.