Hitachi Ltd. Healthcare Hitachi Works
℅ Mr. Jonathan Kahan
Regulatory Counsel
Hogan Lovells US LLP
555 13th Street NW
WASHINGTON DC 20016

August 15, 2018

Re: K181676
Trade/Device Name: Mini Ridge Filter and auxiliary functions for PROBEAT-V
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: June 25, 2018
Received: June 25, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K181676

Device Name

PROBEAT-V

Indications for Use *(Describe)*

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.

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**
**PROBEAT-V**

## Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Telephone: +81 (294) 555232
Facsimile: +81 (294) 559946

Contact Person: Tomoyuki Seino

Date Prepared: July 31, 2018

## Name of Device and Name/Address of Sponsor

PROBEAT-V

Hitachi, Ltd.
3-1-1 Saiwai-cho, Hitachi-shi, Ibaraki-ken, 317-8511
Japan

## Common or Usual Name

Proton beam therapy system

## Classification Name

Medical Charged-Particle Radiation Therapy System, 21 CFR 892.5050, Product Code LHN

## Predicate Devices

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

## Intended Use / Indications for Use

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.

## Technological Characteristics

The PROBEAT-V 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 equipment to perform the above work is composed of two main components: (1) a beam delivery system properly delivered and (2) equipment necessary to generate the proton beam and direct it to the beam delivery system for patient treatment.

The beam delivery system is composed of the following components

- Gantry Room
  - Rotating Gantry
  - Scanning Nozzle
  - Patient Positioning System
  - Cone Beam CT / X-ray Imaging System
- Fixed Beam Room
  - Scanning Nozzle
  - Patient Positioning System
  - Cone Beam CT / X-ray Imaging System

The beam production system is composed of the following components

- Accelerator system (LINAC, Synchrotron)
- Beam transport system (Low/High Energy Beam Transport systems)

The system incorporates several optional features and accessories, namely:

- The Mini Ridge Filter ("mRF") is an optional accessory to modify the beam of the PROBEAT-V system. The mRF is installed manually and may be used in conjunction with the range shifters inside the nozzle or extended range shifter. The mRF can be added to the cleared PROBEAT-V nozzle to spread out the Bragg peak along the axis of the beam in order to reduce the amount of beam energy in the delivery of proton radiation to defined target volumes.

- Beam gating function allowing for interface with cleared external gating systems to control the beam delivery for treatment such as to synchronize irradiation with respiration. Although the overall treatment time tends to be longer than the treatment time without gating, the extension of the treatment time will not affect irradiation performance to the target treatment site. Instead, the gating functionality may limit radiation exposure to regions outside of the target treatment volume.

- Allows for use of fluoroscopy during proton irradiation at the physician's discretion. Fluoroscopy may be used for observation of treatment site during treatment, which could be used for interruption of the treatment or analysis for treatment planning.

**Performance Data**

The company performed the following testing for the additional optional features described above.

- With the mRF (mPF) installed in the nozzle to evaluate range loss, distal dose falloff, and beam spot size.

- The external beam gating function testing was performed to ensure that the PROBEAT-V system receives appropriate signals to interface with external gating systems and provide adequate gating function.

- Testing was performed to ensure that fluoroscopy could be enabled/disabled during proton irradiation without compromising proton dose monitoring.

All tests were successful and confirmed the performance of these additional optional features.

**Substantial Equivalence**

The modified PROBEAT-V with Mini Ridge Filter and auxiliary functions 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. The addition of the optional functions and accessories in the modified version of the system does not raise different questions of safety or effectiveness compared to the predicate. The testing to evaluate the modified device is substantially similar to the testing performed with the predicate device. Thus, the PROBEAT-V with the addition of these optional accessories and features is substantially equivalent to the previously cleared PROBEAT-V.