DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 13, 2016

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

Re: K161163
Trade/Device Name: PROBEAT-V Proton Beam Therapy System with X-ray Limiting Accessory
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: April 25, 2016
Received: April 25, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K161163

Device Name

PROBEAT-V Proton Beam Therapy System with X-ray Limiting Accessory

Indications for Use *(Describe)*

The PROBEAT-V with X-ray Limiting Accessory is a medical devices 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.

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510(k) SUMMARY

PROBEAT-V Proton Beam Therapy System with X-ray Limiting Accessory

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

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Contact Person: Naoya Nishimura

Date Prepared: June 30, 2016

Name of Device and Name/Address of Sponsor

PROBEAT-V Proton Beam Therapy System with X-ray Limiting Accessory

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

Common or Usual Name

Accessory to proton beam therapy system

Classification Name

Medical Charged-Particle Radiation Therapy System, 21 C.F.R. § 892.5050, Product Code LHN

Predicate Devices

PROBEAT-V (K152592)

Intended Use / Indications for Use

The PROBEAT-V with X-ray Limiting Accessory 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 with X-ray Limiting Accessory 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 whose primary responsibility is to ensure that the desired prescription parameters are properly delivered and (2) equipment necessary to generate the proton beam and direct it to the beam delivery system for patient treatment.

The X-ray Beam Limiting accessory for use in conjunction with the cleared PROBEAT-V system is designed to limit the patient's X-ray exposure during imaging for patient positioning with the Cone Beam CT (CBCT). The device has 4 motorized leaves which are controlled by the PROBEAT-V imaging software to position the leaves in order to limit the patient's radiation exposure during patient positioning.

Performance Data

Testing was performed to evaluate that the integration of the X-ray Beam Limiting Device with the previously cleared PROBEAT-V does not impact the performance of the system. This testing evaluated slice pitch accuracy, spatial accuracy, spatial resolution, and isocenter accuracy as well as testing with the proton beam therapy positioning system. Electrical safety was evaluated and electromagnetic compatibility testing was performed with the integrated system. In all cases, the device performed as intended and met all pre-specified success criteria.

Substantial Equivalence

The PROBEAT-V with integrated X-ray beam limiting device accessory for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation is substantially equivalent to the cleared PROBEAT-V system. Both the current and cleared devices have the exact same intended use and substantially similar indications for use and technological characteristics. The addition of the X-ray beam limiting accessory to the system does not alter the intended therapeutic effect of the device system, and does not raise new or different questions of safety or efficacy. The addition of this accessory simply allows for minimizing radiation exposure during image acquisition and patient positioning. Thus, the PROBEAT-V Proton Beam Therapy System with X-ray Limiting Accessory is substantially equivalent to its predicate.