



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

April 21, 2016

Re: K153614

Trade/Device Name: PROBEAT-V and Accessories
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: March 28, 2016
Received: March 28, 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

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

Indications for Use

510(k) Number (if known)

K153614

Device Name

PROBEAT-V and Accessories

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.

The PROBEAT-V includes optional accessories to assist the radiation oncologist in the delivery of proton radiation to defined target volumes while sparing surrounding normal tissue and critical organs from excess 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Accessories to the PROBEAT-V Proton Beam Therapy Systems

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

Hitachi, Ltd., Health Care Company
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Facsimile: +81 (3) 45642882

Contact Person: Naoya Nishimura

Date Prepared: March 28, 2016

Name of Device and Name/Address of Sponsor

Accessories to the PROBEAT-V Proton Beam Therapy Systems

Hitachi, Ltd. Power Systems Company
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, 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.

The PROBEAT-V includes optional accessories to assist the radiation oncologist in the delivery of proton radiation to defined target volumes while sparing surrounding normal tissue and critical organs from excess 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 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.

(1) Change to Minimum MU

The minimum MU of the PROBEAT-V 510(k) (K151132 and K152592) has been reduced to allow for more precise dose distribution utilizing the exact same spot size as previously cleared.

(2) High Accuracy Camera for Patient Positioning System

The high accuracy camera system is a supplemental system for the Patient Positioning System (PPS) which enables enhanced PPS positioning accuracy. The camera system used for enhanced PPS positioning accuracy provides additional feedback to the couch motion control and position correction functions to improve the positioning accuracy. The system comprises an Infrared (IR) camera (optical tracker) and multi-sided probes (MSP) with IR LEDs, and the MSPs are mounted on the couch. The couch position is measured by the camera and the data are then transmitted to the PPS.

Performance Data

The company performed testing to evaluate the dose accuracy, tolerance confirmation for the reduction of minimum MU and the position accuracy for PPS accuracy upgrade. All the tests were successfully conducted and confirmed that the device meets the pre-defined acceptance criteria.

Substantial Equivalence

The PROBEAT-V with the alternate settings and optional accessories 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 as both the current and cleared devices have the same intended use, and substantially similar indications for use and technological characteristics. The addition of the optional settings and accessories to the system do not alter the intended therapeutic effect of the device system, and do not raise new or different questions of safety or efficacy. Specifically, the options are simply minor modifications to components of the cleared PROBEAT-V device to allow for greater precision in the positioning of the patient and the delivery of the treatment dose to the patient. Accordingly, the modified PROBEAT-V is substantially equivalent to the cleared PROBEAT-V.