



Food and Drug Administration  
10903 New Hampshire Avenue  
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Hitachi, Ltd., Health Care Company  
% Mr. Jonathan Kahan  
Regulatory Counsel  
Hogan Lovells US LLP  
555 13<sup>th</sup> Street NW  
WASHINGTON DC 20016

October 2, 2015

Re: K152207

Trade/Device Name: Extended Range Shifter  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical charged-particle radiation therapy system  
Regulatory Class: II  
Product Code: LHN  
Dated: August 6, 2015  
Received: August 6, 2015

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

**Indications for Use**

510(k) Number (if known)

**K152207**

Device Name

Extended Range Shifter

Indications for Use (Describe)

The Extended Range Shifter is an accessory to the PROBEAT-V system that is intended 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

### Extended Range Shifter

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

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Contact Person: Naoya Nishimura

Date Prepared: August 6, 2015

#### Name of Device and Name/Address of Sponsor

Extended Range Shifter

Hitachi, Ltd. Power Systems Company  
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 CFR 892.5050, Product Code LHN

#### Predicate Devices

Hitachi Ltd. PROBEAT-V (K151132)

Varian Proton Therapy Multileaf Collimator (K093250)

#### Intended Use / Indications for Use

The Extended Range Shifter is an accessory to the PROBEAT-V system that is intended 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

This accessory is added to the nozzle of the cleared PROBEAT-V to suppress the beam spreading further compared to use of the standard range shifter.

## **Performance Data**

The company performed testing to evaluate range loss, distal dose falloff, and beam spot size. All the tests were successfully conducted and confirmed the performance of the ERS.

## **Substantial Equivalence**

The ERS is an accessory that may be used with the PROBEAT-V, and is substantially equivalent to the Range Shifter component of the PROBEAT-V (K151132) and the Varian Proton Therapy Multileaf Collimator (K093250). The ERS has the exact same intended use and substantially similar indications for use and technological characteristics as the previously cleared predicate devices. Any minor differences in the technology of these devices and how they are used in a proton beam therapy system do not raise different questions of safety or efficacy. Thus, the ERS is substantially equivalent to its predicates.