Hitachi, Ltd. Radiation Oncology Systems, Kashiwanoha
℅ Jonathan Kahan
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
WASHINGTON DC 20004

December 15, 2022

Re: K220883
Trade/Device Name: Small Field Applicator
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: LHN
Dated: March 25, 2022
Received: March 25, 2022

Dear Jonathan 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 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 -S

Digitally signed by Lora D. Weidner -S
Date: 2022.12.15 21:15:47 -05'00'

Lora Weidner
Assistant Director
DHT8C: Division of Radiological Imagaing and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K220883

Device Name

Small Field Applicator

Indications for Use *(Describe)*

The Small Field Applicator 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.

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510(k) SUMMARY

Hitachi Ltd.'s PROBEAT-CR Proton Beam Therapy Device

K220883

Submitter

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Tiba, 277-0871, Japan
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Contact Person: Tomoko Irisa

Date Prepared: November 16, 2022

Name of Device:

Small Field Applicator

Common or Usual Name:

Proton Beam Therapy Device

Classification Name:

System, Radiation Therapy, Charged-Particle, Medical

Regulatory Class:

Class II

Product Code:

LHN

Predicate Device

PROBEAT-V (K151132)

Reference Device

Extended Range Shifter (K152207)

Device Description

Small Field Applicator is an optional accessory to the proton beam therapy system which can be added to the nozzle configuration of the cleared PROBEAT-V system to make the lateral penumbra sharp, as needed. The Small Field Applicator may be used in place of the optional

removable Applicator having an aperture (collimator) that has been cleared as part of the PROBEAT-V system.

The Small Field Applicator is composed of a cylinder part with touch sensors, a 4-legged table, and a plate part. The Small Field Applicator is inserted at the end of the nozzle to obtain a sharp lateral penumbra in the lateral dose distribution, and it can reduce the dose to the surrounding normal tissue than the case in which the Small Field Applicator is not used.

Intended Use / Indications for Use

The Small Field Applicator 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.

Summary of Technological Characteristics and Comparison to the Predicate device

Both the subject and the predicate device's applicator are accessories to a proton beam therapy system to better direct the proton irradiation to the target anatomy. In each case, the accessories focus the beam by placing an object either in the beam line or surrounding the beam in order to shape the beam. The Small Field Applicator has an aperture (patient collimator) inside similar to PROBEAT-V's applicator. The Small Field Applicator can also optionally be equipped with a range shifter on the nozzle side, and its placement is similar to the PROBEAT-V's applicator. The Small Field Applicator achieves a sharp beam by setting the collimator closer to the patient. Both the Small Field Applicator and the PROBEAT-V's applicator include a touch sensor that will stop the gantry and PPS when the applicator touches the patient. The touch sensor function is same between the Small Field Applicator and PROBEAT-V's applicator. In conclusion, the Small Field Applicator's structure is similar to the PROBEAT-V's applicator and does not affect the Indications for Use and safety function of the device as a whole.

Performance Data

Mechanical testing as well as evaluations to assess the interface with the control system, dose distribution, end-to-end testing to evaluate use in the clinical workflow, and radiation safety have been performed. In all instances, the PROBEAT-V with the Small Field Applicator performed as intended and as safe and effective as the predicate device.

Conclusions

The Small Field Applicator has the same intended use and indications for use as the predicate device. Both devices are accessories to Proton Beam Therapy System and intended to assist radiation oncologist in the delivery of proton radiation to defined target volumes. Performance testing has demonstrated that the Small Field Applicator performs as intended and raises no new questions of safety and effectives compared to the predicate device. Thus, the device can be found substantially equivalent to the identified predicate.