December 26, 2017

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

Re: K171049
Trade/Device Name: Real Time Image Gating System for Proton Beam Therapy Systems
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: December 1, 2017
Received: December 1, 2017

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.

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.

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K171049

Device Name

Real Time Image Gating System for Proton Beam Therapy Systems

Indications for Use *(Describe)*

The Real Time Image Gating System for Proton Beam Therapy Systems is intended for use with compatible Hitachi proton beam therapy systems and is designed to generate gating signals to deliver a proton beam when the position of a fiducial marker, which is implanted near a tumor and tracked by use of X-ray fluoroscopy, is within a given tolerance from its planned position.

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.

510(k) SUMMARY

Hitachi Ltd.'s Real Time Image Gating System

Submitter

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Date Prepared: April 7, 2017

Name of Device:

Real Time Image Gating System for Proton Beam Therapy Systems

Common or Usual Name:

System, radiation therapy, charged-particle, medical

Classification Name:

Medical charged-particle radiation therapy system (21 CFR 892.5050)

Regulatory Class:

Class II

Product Code:

LHN

Predicate Devices

K133914 MedCom GmbH's Verisuite
K131965 Elekta Ltd.'s XVI R5.0

Reference Devices

K160432 Anzai Medical's AZ-733VI

Device Description

The Real-time Image Gating System for proton beam therapy (RGS) is a gating signal generator accessory to proton beam therapy systems (PBTS) and used to track an implanted fiducial and to control the proton beam. The RGS is installed on the PBTS workstation and receives information from the PBTS imaging systems, processes the images, and sends timing signals to the PBTS irradiation controller.

This RGS system recognizes the position of a fiducial marker in the human body at a regular frame rate using the X-ray imaging systems. The marker is implanted near the tumor using image guided implantation. Using two diagnostic X-ray sources and two X-ray FPDs configured around the treatment isocenter, the imaging data are combined to obtain precise 3D trajectories in the RGS. The RGS tracks the implanted marker on the image, and this chosen marker's position viewed in 3 dimensions. Using X-ray fluoroscopy devices in two distinct planes, the location of marker on the fluoroscopic image is automatically extracted using the pattern recognition technology of the RGS and the spatial position of the marker is calculated and monitored throughout the treatment. Synchronized irradiation of the tumor with gating control occurs only when the marker is within a given tolerance from its planned coordinates relative to the beam isocenter. This synchronized irradiation is performed at high speed which enables accurate irradiation of a tumor whose position may move inside the body, e.g., due to respiration.

Intended Use / Indications for Use

The Real-time Image Gating System is intended for use with compatible Hitachi proton beam therapy systems and is designed to generate gating signals to deliver a proton beam when the position of a fiducial marker, which is implanted near a tumor and tracked by use of X-ray fluoroscopy, is within a given tolerance from its planned position.

Summary of Technological Characteristics

The RGS is a software-based accessory installed in the PBTS workstation and receives information from the PBTS imaging systems, processes the images, and sends timing signals to the PBTS irradiation controller. Similarly, the Verisuite and XVI predicates use software-based image processing systems for verification.

This RGS system recognizes the position of a fiducial marker in the human body at a regular frame rate using the fluoroscopic X-ray imaging systems of the PBTS. Similarly, the Verisuite and XVI use fluoroscopic X-ray during treatment to identify implanted fiducial markers.

Although neither the XVI nor the Verisuite includes a gating functionality, each can be used with separately-controlled gating system. Although the inclusion of the gating functionality could impact the safety or effectiveness of the device, it does not raise new questions of safety or effectiveness. In addition, other legally-marketed devices with respiratory gating systems have been cleared by the agency to control the delivery of radiation therapy, including Anzai Medical's AZ-733VI respiratory gating system (K160432). The gating of the proton beam is an

additional safety feature of the RGS that reduces proton beam exposure to areas outside of the target treatment area

Performance Data

The following tests were performed to establish equivalence of the Real Time Gating System:

- Dose measurement of fluoroscopic X-ray at the isocenter and skin surface position on the X-ray tube side
- Recognition accuracy of a static fiducial marker
- System latency
- Tracking of moving marker
- Interlock interface testing
- Interplay effect

Conclusions

The Real Time Gating System is as safe and effective as the VeriSuite and XVI devices. The Real Time Gating System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the Real Time Gating System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Real Time Gating System is as safe and effective as the predicate devices. Thus, the Real Time Gating System is substantially equivalent.