DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Mitsubishi Heavy Industries, Ltd. October 21, 2015
% Mr. Katsuhisa Toyama
Senior Administrator, Business Development Department
4-6-22 Kan-on-shin-machi, Nishi-ku
Hiroshima-shi, Hiroshima-ken 733-8553
JAPAN

Re: K152867
Trade/Device Name: MHI-TM2000 Linear Accelerator System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 28, 2015
Received: September 30, 2015

Dear Mr. Toyama:

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,

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 below.

510(k) Number *(if known)*
K152867

Device Name

MHI-TM2000 Linear Accelerator System

Indications for Use *(Describe)*

MHI-TM2000 Linear Accelerator System is intended for radiation therapy of lesions, tumors and conditions anywhere in the body where radiation treatment is indicated.

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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HIROSHIMA, 733-8553 JAPAN

510(k) Summary
MHI-TM2000 Linear Accelerator System

The following information is provided following the format of 21 CFR 807.92 for the MHI-TM2000 Linear Accelerator System.

Date prepared: September 17, 2015

1. Submitter: Mitsubishi Heavy Industries, Ltd.
Machinery, Equipment & Infrastructure
4-6-22 Kan-on-shin-machi, Nishi-ku, Hiroshima
733-8553 Japan
Establishment Registration Number: 3006942329
Contact person: Shuji Kaneko
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2. Name of the Device:

Trade Name:	MHI-TM2000 Linear Accelerator System/ Vero/ Imavis
Common or Usual name:	Clinical Linear Accelerator
Classification Name:	Medical Charged Particle Radiation Therapy System 21CFR §892.5050, Class II Product Code: IYE

3. Predicate devices to claim substantial equivalence:

MHI-TM2000 Linear Accelerator System: K122450

4. Description of the Device:

The MHI-TM2000 Linear Accelerator System (hereinafter called "**MHI-TM2000 (Ver. 3.5)**") is an Image-Guided Radiation Therapy device generating 6MV high energy X-ray for precision radiation therapy of tumors and conditions, where radiation treatment is indicated.

It includes a linear accelerator, multi-leaf collimator, electric portal imaging device and couch. It also includes O-ring-type gantry platform, X-ray-head-mounted gimbals, Built-in Imaging System, and function to continuously align treatment beam with moving target for precise radiotherapy of

moving targets, as notable characteristics.

The MHI-TM2000 (Ver. 3.5) has been developed based on MHI-TM2000 Linear Accelerator System previously cleared by FDA under K122450 (hereinafter called **"MHI-TM2000 (K122450)**").

Modification was made for introducing a method of radiation therapy called "Dynamic WaveArc" ("DWA") that delivers radiation while rotating both O-ring-shaped gantry (Gantry rotation) and rotational floor of the gantry that moves entire gantry (Ring rotation), or rotating the Ring rotation only.

Radiation type, energy, and the method of generating radiation are identical between MHI-TM2000 (Ver. 3.5) and MHI-TM2000 (K122450)

5. Intended Use Statement:

MHI-TM2000 Linear Accelerator System is intended for radiation therapy of lesions, tumors and conditions anywhere in the body where radiation treatment is indicated.

Indications for Use Statement:

MHI-TM2000 Linear Accelerator System is intended for radiation therapy of lesions, tumors and conditions anywhere in the body where radiation treatment is indicated.

6. Technological Characteristics:

Comparison to the predicate device is listed below:

Feature	MHI-TM2000 (Ver. 3.5)	MHI-TM2000 (K122450)
"Dynamic WaveArc" radiation therapy method	Yes	No

This is the only modification and all other technological characteristics are identical between MHI-TM2000 (Ver. 3.5) and MHI-TM2000 (K122450), such as Indications for use, Operation principles and Method of operation.

7. Summary of Performance Testing:

The design control procedures applied to the development of MHI-TM2000 (Ver. 3.5) includes requirements reviews, risk analysis, and verification and validation testing according to:.

-ISO14971: Risk Management Standard

-FDA Quality System regulation (21 CFR 820) and ISO13485: Quality Management System Standard

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-Other international standards listed in "8. Standards conformance" below in 8.

Result of verification testing, including regression testing, showed conformance to applicable requirements specifications, assured hazard safeguards functioned properly.

Result of validation testing showed conformance to customer needs and intended use of the MHI-TM2000 (Ver. 3.5).

8. Standards conformance:

The MHI-TM2000 (Ver. 3.5) conforms with the FDA recognized consensus standards and other international standards listed below.

IEC 60601-1, IEC 60601-1-2, IEC 60601-2-1
IEC 60601-2-28, IEC 60825-1, IEC 60976, IEC 62304
ISO13845, ISO14971

9. Conclusion:

The verification and validation testing results from bench testing, including regression testing, support the substantial equivalence of the MHI-TM2000 (Ver. 3.5) with MHI-TM2000 (K122450)

A special 510(k) is applicable to this application due to the following reasons:

-Change/ modification does not significantly affect safety and effectiveness of MHI-TM2000 (K122450);
-There is no change in basic design control activities specified in 21CFR 820.30;
-There is no change in the medical device information specified in 21CFR 807.87;
-There is no change in all Labeling including Indications for Use;
-There is no change in fundamental scientific technologies; and
-There is no change in material used.