K122450

OCT 3 2012

**MITSUBISHI HEAVY INDUSTRIES, LTD.**
**MACHINERY & STEEL INFRASTRUCTURE SYSTEMS**
6-22, 4-CHOME, KAN-ON-SHIN-MACHI, NISHI-KU
HIROSHIMA, 733-8553 JAPAN

TELEPHONE :
+80-82-291-2153
FAX :
+80-82-294-9888

## 510(k) Summary

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

1. **Submitter:** Mitsubishi Heavy Industries, Ltd.
Machinery & Steel Infrastructure Systems
4-6-22 Kan-on-shin-machi, Nishi-ku, Hiroshima
733-8553 Japan

Contact person: Yoichi Wakiyama, Manager
Quality Management Team
Phone: +81-82-291-2135
Fax: +81-82-294-9878
E-mail: yoichi_wakiyama@mhi.co.jp

Establishment Registration Number: 3006942329

Date prepared: July 20, 2012

2. **Name of the Device:** MHI-TM2000 Linear Accelerator System
Trade / Proprietary Name: MHI-TM2000 Linear Accelerator System
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:**
1) Mitsubishi Heavy Industries, Ltd.
MHI-TM2000 Linear Accelerator System - **K072047**

**MITSUBISHI HEAVY INDUSTRIES, LTD.**
**MACHINERY & STEEL INFRASTRUCTURE SYSTEMS**
6-22, 4-CHOME, KAN-ON-SHIN-MACHI, NISHI-KU
HIROSHIMA, 733-8553 JAPAN

TELEPHONE :
+80-82-291-2153
FAX :
+80-82-294-9888

**4. 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.

**5. Description of the Device:**

The MHI-TM2000 Linear Accelerator System (hereinafter called "MHI-TM2000 (VER. 3.0)") has been developed based on MHI-TM2000 Linear Accelerator System previously cleared by FDA under K072047 (hereinafter called "MHI-TM2000 (K072047)").

MHI-TM2000 (VER. 3.0) introduces a new interface functionality for remotely controlling gimbaled motion (pan and tilt motion) of X-ray tube and MLC, based on position data received from radiation therapy positioning system "ExacTrac Vero", which is compatible 3rd party device manufactured by Brainlab AG. This functionality enables continuous alignment of treatment beam with moving target resulting in precise radiation treatment of moving targets.

The gimbal mechanism (pan and tilt) is one of the unique characteristics of MHI-TM2000 (K072047), which is called "X-ray-head-mounted gimbals".
The "X-ray-head-mounted gimbals" have been used to compensate for the residual mechanical deformation, mainly caused by gravity, but the MHI-TM2000 (VER. 3.0) utilizes this mechanism further for moving treatment-X-ray beam axis for continuously aligning it with moving target.

A new interface (communication board) for receiving position data is equipped to System Controller Panel of MHI-TM2000 (VER. 3.0).

The method of generating radiation and irradiation are the same as MHI-TM2000 Linear Accelerator System (K072047).

**6. Substantial equivalence:**

The MHI-TM2000 (VER.3.0) is substantially equivalent to the predicate device: MHI-TM2000 Linear Accelerator System (K072047) of Mitsubishi Heavy Industries, Ltd., as Image-Guided Radiation Therapy Equipment. The intended use, indications for use, scientific technologies,

**MITSUBISHI HEAVY INDUSTRIES, LTD.**
**MACHINERY & STEEL INFRASTRUCTURE SYSTEMS**
6-22, 4-CHOME, KAN-ON-SHIN-MACHI, NISHI-KU
HIROSHIMA, 733-8553 JAPAN

TELEPHONE :
+80-82-291-2153
FAX :
+80-82-294-9888

materials, principles of operation and labeling, are the same or equivalent to MHI-TM2000 Linear Accelerator System (K072047).

**7. Summary of Performance Testing:**

The verification testing results from bench testing support the substantial equivalence of the MHI-TM2000 (Ver. 3.0) with the predicate devices.

The result also ensured conformance to system specifications, functional requirements, use cases, hazard mitigation, as well as compliance with applicable standards.

Accuracy of gimbaled (pan and tilt) motion of X-ray tube and MLC (treatment beam axis) to continuously align with moving target, has also been tested because this is the key function for the new functionality. The results also showed that MHI-TM2000 (Ver.3.0) meet the acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Yoichi Wakiyama
Manager, Quality Management Team
Mitsubishi Heavy Industries, Ltd.
Machinery & Steel Infrastructure Systems
4-6-22 Kan-on-shin-machi, Nishi-ku
Hiroshima-shi
733-8553 JAPAN

OCT 3 2012

Re: K122450
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: August 3, 2012
Received: August 13, 2012

Dear Mr. Wakiyama:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

**MITSUBISHI HEAVY INDUSTRIES, LTD.**
MACHINERY & STEEL INFRASTRUCTURE SYSTEMS
6-22, 4-CHOME, KAN-ON-SHIN-MACHI, NISHI-KU
HIROSHIMA, 733-8553 JAPAN

TELEPHONE :
+80-82-291-2153
FAX :
+80-82-294-9888

# Indications for Use Statement

510(k) Number (if known): K122450

Device Name: MHI-TM2000 Linear Accelerator System

**Indications for Use:**

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

Prescription Use X OR Over-the-counter _____
(Per 21 CFR § 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K122450