K122451

510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS FOR EXACTRAC VERO

SEP 28 2012

Manufacturer:	Brainlab AG Kapellenstrasse 12 85622 Feldkirchen Germany Phone: +49 89 99 15 68 0 Fax: +49 89 99 15 68 33
Submitter:	Rainer Birkenbach
Contact person:	Alexander Schwiersch
Summary date:	8/9/2012
Device:	ExacTrac Vero
Trade name:	ExacTrac® Vero
Common/Classification Name:	Patient Positioning System, Radiation Therapy, Charged-Particle, Medical
Predicate Device:	ExacTrac 3rd Party (K072046) Synchrony® Respiratory Tracking System (K120233) by Accuray Inc.
Device classification name:	System, Radiation Therapy, Charged-Particle, Medical
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.5050
Product Code:	IYE
Indication for use	ExacTrac Vero is intended to be used in conjunction with the MHI-TM2000 radiation therapy linear accelerator system manufactured by Mitsubishi Heavy Industries, Ltd. ExacTrac Vero uses the images received from the MHI-TM2000 linear accelerator for analyzing the current patient position and calculating - when applicable - a necessary correction shift. The correction shift is then exported to the MHI-TM2000 linear accelerator. ExacTrac Vero uses stereoscopic x-ray or cone beam CT registration and optical tracking of infrared reflective markers in order to localize and correct the patient position before and during treatment. Optionally ExacTrac Vero provides position data for the pan/tilt motion of the TM2000 gantry head to the MHI-TM2000 controller for continuous alignment of the beam orientation with a moving target. The position data is based on target detection via X-ray imaging and IR tracking of external surrogate markers.

Device description:

ExacTrac Vero is a patient positioning and monitoring system for the MHI-TM2000 Linear Accelerator System by Mitsubishi Heavy Industries Ltd, providing the following main features:

- Patient positioning based on comparison between X-ray images and CT data provided by a treatment planning system.
- Patient positioning based on comparison between Cone Beam CT data and CT data provided by a treatment planning system.
- Optionally providing position data for the pan/tilt motion of the MHI-TM2000 gantry head controller for continuous alignment of the beam orientation with a moving target. The position data is based on infrared tracking of external surrogate markers and the calculated correlation between those external markers and implanted marker positions as detected in X-ray images.
- Monitoring of the patient position during treatment.

Technological characteristics and substantial equivalence:

The following main functionalities were already available for the predicate device ExacTrac 3rd Party (K072046) and have been found to be substantially equivalent:

- Patient positioning based on comparison between X-ray images, provided by an Imaging Device of the MHI-TM2000 Linear Accelerator System, and CT data provided by a treatment planning system.
- Patient positioning based on comparison between Cone Beam CT data, provided by an Imaging Device of the MHI-TM2000 Linear Accelerator System, and CT data provided by a treatment planning system.
- Both modalities can be based on anatomical landmarks or implanted markers.
- Monitoring of the patient position during treatment.

The new functionality for treatment of moving targets was found to be substantially equivalent with the predicate device Synchrony® Respiratory Tracking System (K120233) by Accuray Inc.
This new feature provides position data for the pan/tilt motion of the MHI-TM2000 gantry head controller for continuous alignment of the beam orientation with a moving target. The position data are based on infrared tracking of external surrogate markers and the calculated correlation between those external markers and implanted marker positions as detected in X-ray images.

Changes to Predicate Device ExacTrac 3rd Party (K072046):

ExacTrac Vero introduces a new functionality that provides in combination with the MHI-TM2000 linear accelerator the option of aligning the treatment beam with moving targets. This new function provides position data for the pan/tilt motion of the MHI-TM2000 gantry head controller for continuous alignment of the beam orientation with the breathing induced movement of the target.

Statement regarding nonclinical tests:

When verifying the design the following methods were used:

- Software memory leakage tests using special libraries or tools.
- Software stress tests with e.g. random input, low memory conditions, network failure, low, high, positive/negative values, etc.
- Stepping through the code using the debugger focusing on the data flow.
- Check every compiler warning and remove the cause for the warning (although some warnings still remain due to old code basis).
- Code reviews.
- Use of a dynamic analysis tool.
- Usability tests, prototyping and tests in simulated environment.
- Worst case analysis of an assembly to verify that components are designed properly and not subject to overstress during handling and use.
- Drawing review.
- Stress tests of material to verify that it does not break, including safety margins i.e. 4x or 8x its weight.
- Biocompatibility tests.
- Prototyping.
- EMC testing in accredited laboratory.
- Testing in clinical similar environment for usability.

Statement regarding clinical performance data

For the clinical evaluation the following validation methods and data sources have been used:

- Literature review.
- Simulated treatment of anthropomorphic human-bone phantoms within a simulated clinical environment.
- Retrospective analysis of correlation between breathing and tumor motion.
- Analysis of existing x-ray image sets acquired during routine clinical use of predicate devices.

Conclusions

ExacTrac Vero has been verified and validated according to Brainlab procedures for design and development. The verification and validation proves the safety and effectiveness of the system. The information provided by Brainlab in this 510 (k) application was found to support a substantial equivalence decision.

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. Alexander Schwiersch
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Brainlab AG-R&D RT
Kapellenstraße 12
Feldkirchen, Bavaria 85622
GERMANY

SEP 28 2012

Re: K122451
Trade/Device Name: Exactrac Vero
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: August 9, 2012
Received: August 13, 2012

Dear Mr. Schwiersch:

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

INDICATION FOR USE

510(k) Number (if known): K122451

Device name: ExacTrac Vero

Indication for use:

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ExacTrac Vero uses the images received from the MHI-TM2000 linear accelerator for analyzing the current patient position and calculating - when applicable - a necessary correction shift. The correction shift is then exported to the MHI-TM2000 linear accelerator.

ExacTrac Vero uses stereoscopic x-ray or cone beam CT registration and optical tracking of infrared reflective markers in order to localize and correct the patient position before and during treatment.

Optionally ExacTrac Vero provides position data for the pan/tilt motion of the TM2000 gantry head to the MHI-TM2000 controller for continuous alignment of the beam orientation with a moving target. The position data is based on target detection via X-ray imaging and IR tracking of external surrogate markers.

Prescription Use _____X_____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K122451