K072046

OCT 17 2007

510 (k) Summary of Safety and Effectiveness for ExacTrac 3rd Party

Manufacturer:

Address: BrainLAB AG
Kapellenstrasse 12
85622 Feldkirchen
Germany
Phone: +49 89 99 15 68 0
Fax: +49 89 99 15 68 33

Contact Person: Mr. Rainer Birkenbach

Summary Date: May 16, 2007

Device Name:

Trade name: **ExacTrac 3rd Party,** will also be marketed under the name **ExacTrac X-ray 6D 3rd Party, ExacTrac OEM**

Common/Classification Name: Patient Positioning System / System, Radiation Therapy, Charged-Particle, Medical

Predicate Device:
ExacTrac 4.0 (K040585)

Device Classification Name: System, Radiation Therapy, Charged-Particle, Medical
Regulatory Class: Class II

Intended Use:
The ExacTrac 3rd Party system is intended to be used in conjunction with the MHI-TM2000 radiation therapy linear accelerator system manufactured by Mitsubishi Heavy Industries, Ltd.
ExacTrac 3rd Party 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.
The ExacTrac 3rd Party system 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.

Device Description:
ExacTrac 3rd Party is an Image Processing System for patient positioning on the MHI-TM2000 linear accelerator. It is based on an imported isocenter from a planning system or on an isocenter imported from a simulator. It allows verification and, if necessary correction of the patient's position.
Correction of patient's position is based on a comparison of

a) digital reconstructed images (DRR) calculated from a corresponding CT set (reference image) and x-ray images (live images) from the imaging system of the MHI-TM2000 linear accelerator with the patient on the treatment couch.
b) the treatment planning CT and a Cone Beam CT taken on the imaging system of the MHI-TM2000 linear accelerator with the patient on the treatment couch.

The x-ray images, accomplished as stereoscopic x-rays or a Cone Beam CT scan, are created by the corresponding kV x-ray imaging system of the MHI-TM2000 linear accelerator and loaded into the ExacTrac 3rd Party System. Structures on the images to be compared can be either anatomical landmarks or implanted internal markers. Based on the imaging data, ExacTrac 3rd Party determines the correct treatment position, which is then applied by couch motion of the MHI-TM2000 linear accelerator.

Substantial equivalence:
ExacTrac 3rd Party has been verified and validated according to BrainLAB's procedures for product design and development. The validation proves the safety and effectiveness of the system. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate device ExacTrac 4.0 (K040585)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2007

Mr. Rainer Birkenbach
Executive Vice President
BrainLAB AG
Kapellenstraβe 12
85622 Feldkirchen
GERMANY

Re: K072046
Trade/Device Name: ExacTrac 3rd Party (BrainLAB's Patient Positioning System)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 6, 2007
Received: July 25, 2007

Dear Mr. Birkenbach:

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **ExacTrac 3rd Party** (BrainLAB's Patient Positioning System)

Indications For Use:

ExacTrac 3rd Party

The **ExacTrac 3rd Party** system is intended to be used in conjunction with the MHI-TM2000 radiation therapy linear accelerator system manufactured by Mitsubishi Heavy Industries, Ltd.

ExacTrac 3rd Party 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.

The **ExacTrac 3rd Party** system 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.

Prescription Use ____X____ (Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 Reproductive, Abdominal and Radiological Devices
510(k) Number K072046