K072506

510 (k) Summary of Safety and Effectiveness for ExacTrac 5.5

Manufacturer

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Contact Person	Mr. Rainer Birkenbach
Summary Date	July, 2007

OCT 26 2007

Device Name

Device Name	ExacTrac 5.5, will also be marketed under the name ExacTrac X-Ray 6D or Novalis Body
Common Name	Patient Positioning System with respiratory Gating, Radiation Therapy, Charged-Particle, Medical
Classification Name	System, Radiation Therapy, Charged-Particle, Medical
Classification Number	892.5050
Regulatory Class	Class II
FDA Establishment Registration Number	804 39 33

Predicate Device

ExacTrac 4.0(K040585)
ExacTrac Gating (K033287)

X-ray Generator
Device Classification Name: Generator, High Voltage X-Ray, Diagnostic
Regulatory Class: Class I Exempt
Accession Number: 0110172-00

X-ray Tubes
Device Classification Name: Assembly, Tube Housing, X-Ray, Diagnostic
Regulatory Class: Class I Exempt
Accession Number: 7410266-15

Intended Use

ExacTrac is a system that is intended to be used to place patients at an accurately defined point within the treatment beam of a medical accelerator for stereotactic radiosurgery or radiotherapy procedures. The ExacTrac system uses optical tracking of infrared markers and x-ray registration to determine and correct the position of the patient. With the additional ExacTrac gating module, the treatment beam is gated in accordance with the patient's breathing level.

Device Description

ExacTrac 5.5 is an Image Processing System for patient positioning with the ability of a gated treatment. 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.
The correction of the patient's position is based on a comparison of digital reconstructed radiographs (DRR) calculated from a corresponding CT data set (reference image). Alternatively implanted radioopaque markers may be used for localization by comparing their position in the x-ray with their original position in the reference CT data set. Within the Gating module the 3D position of the implanted markers is compared, for at least one breathing level of the patient, to their expected position based on the CT data With the resultant correction values and target movement information the patient is repositioned and the system generates a signal to gate the linear accelerator depending on the patients breathing.

Substantial Equivalence

ExacTrac 5.5 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) combined with ExacTrac Gating (K033287).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2007

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

Re: K072506
Trade/Device Name: ExacTrac 5.5
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 31, 2007
Received: September 6, 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): K072506

Device Name: **ExacTrac 5.5**

Indications For Use:

ExacTrac is a system that is intended to be used to place patients at an accurately defined point within the treatment beam of a medical accelerator for stereotactic radiosurgery or radiotherapy procedures. The ExacTrac system uses optical tracking of infrared markers and x-ray registration to determine and correct the position of the patient. With the additional ExacTrac gating module, the treatment beam is gated in accordance with the patient's breathing level.

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072506

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)