K033287

DEC 1 9 2003

510 (k) Summary of Safety and Effectiveness for ExacTrac® Gating

Manufacturer:

Address: BrainLAB AG
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85551 Heimstetten
Germany
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Contact Person: Mr. Rainer Birkenbach

Summary Date: October 10th, 2003

Device Name:

Trade name: ExacTrac® Gating

Common/Classification Name: ExacTrac® Gating

Predicate Devices:
ExacTrac® (K 003285)
RPM Respiratory Gating System (K983629)

Device Classification Name: Instrument,
Regulatory Class: Class II

Intended Use:

The ExacTrac gating module is an extension to the ExacTrac patient positioning system. ExacTrac Gating repositions the patient relative to the treatment machine according to breathing induced shifts of a target area, and controls the gating of the treatment beam.

Device Description:

ExacTrac® Gating module uses x-ray images acquired before the treatment, to determine the position of fiducial markers that are implanted close to the target region. Via the ExacTrac® infrared cameras, the system can track the breathing motion of IR-reflective markers that are attached to the patient's body. For at least one breathing level of the patient the 3D position of the implanted markers is compared to their expected position based on a previously acquired CT-scan. The patient is then semi-automatically repositioned relative to the treatment machine.
The system generates a signal that can be used to gate a linear accelerator on and off depending on the patients breathing level being in the target region or not.

Substantial equivalence:
The ExacTrac® gating module will be 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 devices ExacTrac® 2.0 (K003285) and RPM Respiratory Gating System (K983629)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2003

Mr. Rainer Birkenbach
Executive Vice-President
BrainLAB AG
Ammerthalstraße 8
85551 Heimstetten
GERMANY

Re: K033287
Trade/Device Name: ExacTrac Gating
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: October 10, 2003
Received: October 14, 2003

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 Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

510(k) Number (if known): K033287

Device Name: ExacTrac Gating

Indications For Use:

The ExacTrac gating module is an extension to the ExacTrac patient positioning system. ExacTrac Gating repositions the patient relative to the treatment machine according to breathing induced shifts of a target area, and controls the gating of the treatment beam.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033287