510(k) Summary of Safety and Effectiveness for ExacTrac 2.0

K003285

JUL 3 1 2001

1. Company

Address: BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany

Contact Person: Stefan Vilsmeier, President
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2. Device Name

Trade name: **ExacTrac**, will also be marketed under the name **Novalis Body**
Common name: Patient Positioning System
Current version number: ExacTrac 2.0
Device Classification name: System, Radiation Therapy, Charged-Particle, Medical

3. Predicate Devices:

ExacTrac (K983660)
Device Classification Name: System, Radiation Therapy, Charged-Particle, Medical
Regulatory Class: Class II

X-Ray Generator
Device Classification Name: Generator, High Voltage X-Ray, Diagnostic
Regulatory Class: Class I Exempt

X-Ray Tubes
Device Classification Name: Assembly, Tube Housing, X-Ray, Diagnostic
Regulatory Class: Class I Exempt

4. Device Description

ExacTrac 2.0 is a Patient Positioning System. 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 patient's position.
Correction of patient's position is based on a comparison of digital reconstructed images (DRR) calculated from a corresponding CT set (reference image) and x-ray images (live images) . Structures on the images to be compared can be either anatomical landmarks or implanted internal markers.
For some applications (e.g. prostate tumors) the correction can alternatively be performed by using the ultrasound module. Here the correction of patient's position is based on a comparison of an outlined structure in the CT set (reference image) and perpendicular ultrasound images (live images) .

5. Intended Use

ExacTrac 2.0 is a system that is intended to be used to place patients at the isocenter of a linear accelerator for stereotactic radiosurgery or radiotherapy procedures. The ExacTrac 2.0 system uses optical tracking of infrared reflecting markers and x-ray registration as the method of locating the position of the patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 1 2001

Mr. Stefan Vilsmeier
President & CEO
BrainLAB AG
AmmerthalstraBe 8
85551 Heimstetten
GERMANY

Re: K003285
ExacTrac 2.0 (patient positioning device)
Dated: April 27, 2001
Received: May 2, 2001
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr.Vilsmeier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 (s)

510(k) Number (if known): K003285

Device Name: **ExacTrac 2.0**
(BrainLAB's Patient Positioning System)

Indications For Use:

ExacTrac 2.0

ExacTrac 2.0 is a system that is intended to be used to place patients at the isocenter of a linear accelerator for stereotactic radiosurgery or radiotherapy procedures. The ExacTrac 2.0 system uses optical tracking of infrared reflecting markers and x-ray registration as the method of locating the position of the patient.

(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 I-2-96)

David A. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K003285/S001