MAY 17 2005 K042543

510 (k) Summary of Safety and Effectiveness for iPlan® Hip Templating

Manufacturer:

Address: BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
Germany
Phone: +49 89 99 15 68 0
Fax: +49 89 99 15 68 33

Contact Person: Mr. Rainer Birkenbach

Summary Date: February 2, 2005

Device Name:

Trade name: iPlan® Hip Templating

Common/Classification Name: Planning System

Predicate Device:
iPlan!® 2 (K020631)

Device Classification Name: Stereotaxic instrument
Regulatory Class: Class II

Intended Use:
The iPlan Hip Templating system is indicated for the preoperative planning of orthopedic treatments. It is specially developed for the preparation and display of anatomical patient data that has been acquired using x-ray, CT or MR equipment.

iPlan Hip Templating creates treatment plans in conjunction with 2D / 3D implant models. Implant models are provided by a separate database. Both 2D and 3D planning are supported, depending on the anatomical information available.

The treatment plan can either be saved or printed as required.

Device Description:
iPlan Hip Templating is a stand-alone system for preoperative orthopedic treatment planning which facilitates digital template planning for anatomical images. Once image scaling has been completed, using an object of known size that is positioned next to the anatomical area of interest during image acquisition, the surgeons can use a range of measurement tools in order to select the optimum implant for the patient. The software overlays 2D / 3D implant models onto the image data and displays the result. The measurement tools can also be used to display preplanned and current values where required.
The digital implant models are provided by a separate implant database. Both 2D implant contours and 3D implant models are available.

K042543

Treatment plans can be saved and printed out as required. The information stored in the treatment plan can be loaded to other BrainLAB applications and used to support image guided surgery in a VectorVision system, for example.

Substantial equivalence:
iPlan® Hip Templating 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 iPlan® (K020631).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2005

Mr. Oliver Fleig
Project Manager
BrainLAB AG
Ammerthalstraße 8
85551 Heimstetten, Germany

Re: K042543
Trade/Device Name: iPlan Hip Templating
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: April 12, 2005
Received: April 19, 2005

Dear Mr. Fleig:

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 (240) 276-0115 . 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 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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 042543

Device Name: iPlan Hip Templating

The iPlan Hip Templating system is indicated for the preoperative planning of orthopedic treatments. It is specially developed for the preparation and display of anatomical patient data that has been acquired using x-ray, CT or MR equipment.

iPlan Hip Templating creates treatment plans in conjunction with 2D / 3D implant models. Implant models are provided by a separate database. Both 2D and 3D planning are supported, depending on the anatomical information available.

The treatment plan can either be saved or printed as required.

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)

General, Restorative
Devices

K042543