K053127

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FEB 9 2006

510 (k) Summary of Safety and Effectiveness for iPlan BOLD MRI

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:	September 29, 2005

Device Name: iPlan

The existent iPlan Planning System should be amended with the module BOLD MRI.

Trade name:	**iPlan** (iPlan Cranial, iPlan Stereotaxy, iPlan ENT, iPlan RT, iPlan NET, iPlan FLOW)
Common/Classification Name:	Planning System/Stereotaxic Instrument

Predicate Device:

BrainLAB iPlan (K041703)

Device Classification Name: Instrument, Stereotaxic

Regulatory Class: Class II

Intended Use:

iPlan's indications for use is to prepare and present patient and image data based on CT, MR, X-ray(Fluoro), including

- image preparation
- image fusion
- image segmentation

where the result is used for the creation of treatment plans for Stereotactic Surgery:

- Surgery Planning

The Surgery Planning is a tool for pre- and intraoperative stereotactic surgery planning based on stereotactic systems. Multiple graphical display functions and 3-dimensional views of anatomical structures offer effective and efficient means of presenting the anatomical data for diagnostic and surgical planning. Computer-graphic simulation in various views of a chosen probe path can help prevent probe intersections with unwanted, critical structures or vessels.

The surgeon can interactively change a probe path simulation through the image slices in the software with on-line calculation of the accompanying arc settings and graphical manipulation to aid in optimizing his approach.

- BrainMAP

The BrainMAP module is a tool, which defines two and three-dimensional information about anatomical structures of the human brain for pre- and intraoperative planning of stereotactic procedures. These contours are defined and described by Talairach/Tournoux and/or Schaltenbrand/Wahren based brain atlases.

The user is provided with information about the position of the various functional and anatomical areas of the brain. These positions of the structures have to be correlated with every patients brain data. The correlation is defined by a procedure defined by Talairach/Tournoux. Using their grid system to divide the brain in particular areas, the program will be able to provide matching data for different patient data. BrainMAP may be used alone or in conjunction with neurosurgery.

- Functional Planning

The Functional Planning is based on Surgery Planning, which gives two- and three dimensional online information of a stereotactical surgical instrument (electrodes) for a neurosurgical functional treatment using a stereotactic arc. The user is provided with information by numerical results and by various displays and reconstruction planes based on patient images (CT, MRI, PET, SPECT) about the position and orientation relative to the patient of his surgical instrument to perform stimulation and treatment on brain structures or to a preplanned trajectory .

The software is capable of displaying the trajectory and functional areas of the brain based on BrainMAP online on the screen and recording the stimulations by storing positions of the electrodes.

The Functional Planning is intended to be used with patients where measurement, stimulation and placement of electrodes in the brain (pallidotomy) are part of the treatment. The stereotactic arc system is useful for placing these electrodes or using the instruments during the treatment and in the planning phases of the functional treatment.

In addition iPlan's indications for use is to prepare and present patient and image data based on CT, MR, X-ray(Fluoro) including

- image preparation
- image fusion
- image segmentation

where the result is preplanned data to be used by other BrainLAB medical devices such as VectorVision (for performing the planned treatment) where these medical devices are used for:

- Image Guided Surgery

BrainLAB's Image Guided Surgery system is intended to be an intraoperative image guided localization system to enable minimally invasive surgery where the image guided surgery system is indicated for any medical condition in which the use of stereotactic surgery may be considered to be appropriate and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT, X-ray or MR based model of the anatomy.

Example procedures include but are not limited to:

- Cranial procedures
- Spine procedures
- ENT procedures

- FiberTracking

FiberTracking's indication for use is to prepare and present patient and image data based on MRI scanned with diffusion-weighted sequences. These diffusion images are used for the calculation and display of fiber bundles in a selected region of interest. The created treatment plans of iPlan! FiberTracking can be used with other iPlan! treatment plans and other BrainLAB medical devices such as VectorVision, where this medical device is used for image guided surgery.

- BOLD MRI

iPlan BOLD MRI indication for use is to prepare image data based on BOLD (blood oxygen level dependent) MRI scan studies and display the result as parametric images. When interpreted by a trained physician or surgeon this information may be used with other anatomical information for planning and image guided surgery.

Device Description:

The BrainLAB iPlan BOLD MRI module is software used for processing BOLD (blood oxygen level dependent) MRI sequences and display of calculation results. The slight MRI susceptibility changes between the images are visualized as parametric images.

Substantial equivalence:

iPlan 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 (K041703).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 9 2006

Mr. Rainer Birkenbach
Executive Vice President
Research and Development
BrainLAB AG
Ammerthalstrasse 8
85551 Heimstetten
GERMANY

Re: K053127
Trade/Device Name: iPlan
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: January 13, 2006
Received: January 17, 2006

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Barbara Melkerson

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: iPlan

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Intended Use:
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(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices
Barbara Brennan

510(k) Number K053127

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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 General, Restorative, and Neurological Devices

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