SEP 2 2 2004 K041330 1/3

510 (k) Summary of Safety and Effectiveness for iPlan!FLOW

Manufacturer:

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Contact Person: Mr. Rainer Birkenbach

Summary Date: May 04, 2004

Device Name:

Trade name: iPlan!FLOW

Common/Classification Name: Planning System/Stereotactic Instrument

Predicate Device:
iPlan!® (K 0206311)

Device Classification Name: Instrument, Stereotactic
Regulatory Class: Class II

Intended Use:
iPlan!FLOW's indications for use incorporate the indications for use of iPlan! and thus is to prepare and present patient related medical image data based on CT and/or MR including

- image preparation
- image fusion
- image segmentation
- display of guideline-visualizations for planning the placement of intra-cranial catheters

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

Stereotactic Surgery:

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.

In addition iPlan!FLOW's indications for use is to prepare and present patient and image data based on CT, MR, X-ray(Fluoro), Angiographic and other imaging sources 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) or 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 or MR based model of the anatomy.
The surgeon can interactively change a probe path simulation through the image slices in the software and graphical manipulate trajectories to optimize his approach. An intra-cranial catheter can be chosen and the path of the catheter can be planned. The user is provided with information by various displays and reconstruction planes based on patient images (CT, MRI, PET, SPECT) about the position and orientation relative to the patient of this catheter on brain structures or to a preplanned trajectory .

iPlan!Flow can visualize guidelines for better placement of intra-cranial catheters. These guidelines comprise the minimal depth of the catheter tip in the brain tissue, the minimal distance of the catheter tip from intra-cranial surfaces and the minimal distance between different catheter tips. This visualization enables the surgeon to better plan and place intra-cranial catheters.

Device Description:
Like iPlan!® (K020631), iPlan!FLOW is a software tool running on a standard, stand-alone computer (PC or Laptop) or being accessible via the intranet connection for pre- or intraoperative planning of treatments based on stereotactic systems or image guided surgery systems.

Unchanged to iPlan!® (K020631) iPlan!FLOW provides e.g. tools for the automatic or manual segmentation of anatomical structures which enables the user such as radiologists or neurosurgeons to quickly achieve the desired segmentation results through an unlimited number of automatic and/or manual re-segmentations. Additionally to the predicate device iPlan! functional data derived from the Diffusion Tensor acquired by Magnetic Resonance Imaging (MRI) like maps of the fractional anisotropy (FA-Maps) and maps of the apparent diffusion coefficient (ADC-Trace-Map) can be displayed and matched with the anatomical data.
In addition to the trajectory-planning capabilities of iPlan!, iPlan!FLOW can be used for the planning of intracranial catheters, with image guided surgery. Guidelines provided by the catheter supplier for the exact placements of intracranial catheters can be visualized. These guidelines comprise the minimal depth of the catheter tip in the brain tissue, the minimal distance of the catheter tip from intra-cranial surfaces and the minimal distance between different catheter tips. This visualization enables the surgeon to better plan and place intra-cranial catheters.

The created treatment plans of iPlan!FLOW can be used on its own or in conjunction with other BrainLAB medical devices such as VectorVision for performing the planned treatment.

Substantial equivalence:
iPlan!FLOW 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

SEP 2 2 2004

Mr. Rainer Birkenbach
Executive Vice President
BrainLAB AG
Ammerthalstrasse 8
Heimstetten,
Germany 85551

Re: K041330
Trade/Device Name: iPlan! FLOW
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: September 6, 2004
Received: September 9, 2004

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K041330

Device Name: iPlan!FLOW

Indications For Use:

iPlan!FLOW is designed as a planning system for pre- and intraoperative planning of stereotactic or image guided surgery treatments. It is specially designed to display anatomical images of a patient acquired with MR and/or CT as well as images derived from DTI-data acquired with Magnetic Resonance Imaging (MRI). iPlan!FLOW has a dedicated tool for planning trajectories of intra-cranial catheters. Guidelines for the catheter placement from the catheter supplier can be visualized and displayed to support the surgeon in improving catheter placement planning. iPlan!FLOW does not generate or create rules for the placement of intracranial catheters by any means. The Primary mode of action for iPlan!Flow is a device for creating treatment plans for stereotactic or image guided surgical treatment.
The treatment plans can be used in conjunction with other BrainLAB medical devices such as VectorVision for image guided surgical treatment.

(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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041330

(Optional Format I-2-96)