MAR 2 3 2006

K053164

Page 1 of 2

510 (k) Summary of Safety and Effectiveness for iPlan Flow

Manufacturer:

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

Contact Person: Mr. Rainer Birkenbach

Summary Date: March 21, 2006

Device Name:

Trade name: iPlan Flow

Common/Classification Name: Planning System/Stereotactic Instrument

Predicate Device:
iPlan!FLOW (K 041330)

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

Intended 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 is a dedicated tool for planning trajectories of intra-cranial catheters. Guidelines for the catheter placement e.g. from catheter suppliers can be visualized and displayed to support the surgeon in improving catheter placement planning. The guidelines, in combination with anatomical information, can be used to suggest areas that are compliant with the guidelines. iPlan Flow does not generate or create rules for the placement of intracranial catheters by any means. iPlan Flow uses MR-DTI and T2-weighted MR images to suggest likely volumes of fluid distribution.

The Primary mode of action for iPlan Flow is a device for creating treatment plans for stereotactic or image guided surgical treatment, especially for the creation of plans for the placement of intra-cranial catheters.

The treatment plans can be used in conjunction with other BrainLAB medical devices such as VectorVision for image guided surgical treatment.

K05 3164

Page 2 of 2

Device Description:
Like iPlan!FLOW (K041330), 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!FLOW (K041330) 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. Like the predicate device iPlan!FLOW (K041330) iPlan Flow can be used for the planning of intracranial catheters, with image guided surgery. Guidelines provided e.g. by the catheter suppliers 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. In addition to the predicate device the depth guideline can be calculated from the flow rate and the catheter diameter and warnings will be displayed if the trajectory of a planned catheter is likely to cross an intra-cranial surface. iPlan Flow is able to calculate a likely fluid distribution from the planned catheter positions to support the physician in his decision about appropriate catheter positions.
These features enable 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!FLOW (K041330).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2006

BrainLAB AG
c/o Mr. Rainer Birkenbach
Ammerthalstrasse 8
85551 Heimstetten
Germany

Re: K053164
Trade/Device Name: iPlan Flow
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: March 8, 2006
Received: March 10, 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.

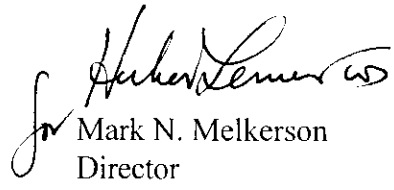
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (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,



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

Enclosure

K053164

Indications for Use

510(k) Number (if known):

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).

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The treatment plans can be used in conjunction with other BrainLAB medical devices such as VectorVision for image guided surgical treatment.

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

510(k) Number K053164