MAY - 7 2012

510(k) Summary- iPlan

1. Manufacturer

Address: Brainlab AG
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85622 Feldkirchen
Germany
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Contact Person: Mr. Alexander Schwiersch

Summary Date: November 17, 2011

2. Device Name

Trade name (*): iPlan Cranial, iPlan Stereotaxy
iPlan ENT, iPlan Spine, iPlan View, iPlan CMF

Common/Classification Name: Planning System, Stereotactic Instrument

3. Predicate Devices

iPlan (K101627)
Maxilim (K052424)

4. Device Description

iPlan is a software based treatment planning application providing functionalities like viewing, processing and documentation of medical data including different modules for image preparation, image fusion, image segmentation where the result is a treatment plan that can be used e.g. for stereotactic and/or image guided surgery.

5. Intended use

iPlan's indications for use are the viewing, presentation and documentation of medical imaging, including different modules for image processing, image fusion, atlas assisted visualization and segmentation, intraoperative functional planning where the output can be used e.g. with stereotactic image guided surgery or other devices for further processing and visualization.

Example procedures include but are not limited to:

- Planning and simulation of cranial surgical procedures such as tumor resection, shunt placement, minimal-invasive stereotactic interventions, biopsy, planning and simulation of trajectories for stimulation and electrode recording

- ENT procedures such as sinus surgery, tumor surgery
- Spine procedures such as tumor surgery, pedicle screw planning, vertebroplasty planning
- iPlan View is an application which is intended to be used for reviewing existing treatment plans
- Planning and simulation of cranio-maxillofacial procedures

Typical users of iPlan are medical professionals, including but not limited to surgeons and radiologists.

6. Technological Characteristics

#	Sub-module	Changed *)	iPlan CMF	iPlan Cranial	iPlan ENT	iPlan Stereotaxy	iPlan Spine	iPlan View
1	Load and Import	No	X	X	X	X	X	X
2	View and Adjustment	No	X	X	X		X	X
3	Registration Points	No	X	X	X	X	X	
4	ACPC Localization	No				X		
5	Localization	No				X		
6	Image Fusion	No	X	X	X	X	X	X
7	Object Creation	No	X	X	X	X	X	
8	Advanced Object Planning	No	X	X	X			
9	BOLD MRI mapping	No		X		X		
10	Fiber Tracking	No		X		X		
11	Trajectory planning	No	X	X	X		X	
12	Stereotactic planning	No				X		
13	Electrode recording	No				X		
14	Save and Export	No	X	X	X	X	X	
15	3D Functionalities	Yes	X	X	X	X	X	X

*) changed compared to iPlan K101627

Description of sub-modules:

#	Sub-module	Description
1	Load and Import	Load existing treatment data from different data sources, Import patient data from DICOM or other archive types, manage (delete/copy/move) patient folders
2	View and Adjustment	Review patient data in various reconstructions or overlay, side-by-side comparison of different modalities, aligning the data set orientation, import or export screenshot images
3	Registration Points	Automatic detection of CT or MR registration markers for navigation, manual placement of markers and anatomical landmarks

4	ACPC Localization	This planning task allows the definition of AC/PC coordinate system
5	Localization	Assign a localizer frame for CT or MRI localization Perform automatic detection of localizer rods
6	Image Fusion	Align available image sets automatically, manually or using landmarks for various combinations of images sets and modalities such as CT, MRI, PET and SPECT. Visual verification of alignment.
7	Object Creation	Outline anatomical structures using manual or automatic segmentation methods. Advanced manipulation for 3D objects with scaling, logical operations and object splitting. Volumetric measurements based on the created 3D objects
8	Advanced Object Planning	Mirror and split segmented structures
9	BOLD MRI mapping	Processing of blood oxygen level dependent (BOLD) MRI data Definition of block design functional task, calculation of activation areas based on BOLD MRI data, time series view for activation signal, creation of 3D objects from activation areas
10	Fiber Tracking	Processing of diffusion tensor imaging (DTI) using various ways to define and combine seed regions of interest. Definition of multiple fiber bundles and creation of 3D objects from fiber bundles. Volumetric measurements and detailed fiber information
11	Trajectory planning	Plan pathways for surgical instruments or resection, definition of entry, target points and diameter for trajectories
12	Stereotactic planning	Planning of stereotactic trajectories Usage of AC/PC coordinates and Schaltenbrandt-Wahren atlas Calculation of stereotactic arc settings for planned trajectories
13	Electrode recording	Planning of parallel electrode tracks Enter and display microelectrode recording and stimulation results, display information stepwise along tracks
14	Save and Export	Save the current treatment plan to the patient folder Export the results to the navigation, as DICOM or STL format
15	3D Functionalities	Three-dimensional volume based rendering for different image modalities and planning data. Extension of standard view types and options with structure specific view types.

7. Assessment of non-clinical performance data: non clinical tests

Usability workshops were performed with prototype versions of the software which has no relevant user interface differences to the final version and is therefore equivalent to the final version in respect to the usability validation.
Moreover an Expert Group Review has worked with Brainlab in order to tailor the existing iPlan planning functionalities to the specific needs of CMF surgeons.

8. Clinical Evaluation/Validation

The clinical evaluation has been based on literature studies.

9. Application performance testing

On different levels of development (module, subsystem, system) specific bench and integration tests were conducted. Internal standards were tested and documented as conformance report, environment compatibility and interfaces. Compatibility with previous version and comparable workflows to predicate devices were documented in corresponding review protocols.

10. Conclusions

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Alexander Schwiersch
Regulatory Affairs Manager
Brainlab AG
Kapellenstrasse 2
85622 Feldkirchen
GERMANY

MAY - 7 2012

Re: K113732
Trade/Device Name: iPlan
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK, LLZ
Dated: April 30, 2012
Received: May 4, 2012

Dear Mr. Schwiersch:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113732

Device Name: iPlan

Indications For Use:
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Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (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 Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113732