K103246

MAR 16 2011

# 510 (k) Summary of Safety and Effectiveness for iPlan RT

**Manufacturer**


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|---|---|
| Address | Brainlab AG<br>Kapellenstr. 12<br>85622 Feldkirchen<br>Germany<br>Phone: +49 89 99 15 68 0<br>Fax: +49 89 99 15 68 33 |
| Contact Person | Mr. Alexander Schwiersch |
| Summary Date | January 19, 2011 |


**Device Name**

| | |
|---|---|
| Device Name | iPlan RT |
| Common Name | System, Planning, Radiation Therapy Treatment |
| Classification Name | Medical charged-particle radiation therapy system |
| Classification Number | 21 CFR 892.5050 |
| Regulatory Class | Class II |
| FDA Establishment Registration Number | 8043933 |

**Predicate Device**

Predicate Device: **iPlan RT Image**
510 (k): **K080886**

Predicate Device: **iPlan RT Dose**
510 (k): **K080888**

## Intended Use

iPlan RT is a radiation treatment planning system that is intended for use in stereotactic, conformal, computer planned, Linac based radiation treatment of cranial, head and neck, and extracranial lesions.

## Device Description

iPlan RT is a software program to generate treatment plans and to simulate the dose delivery for external beam radiotherapy. The system is the evolutionary successor of the predicate devices iPlan RT Image (K080886) and iPlan RT Dose (K080888). It is specialized for stereotactic procedures for cranial as well as extracranial lesions. It includes functions for all relevant steps from outer contour detection to quality assurance. It combines most of its predecessor's functionality iPlan RT Image and iPlan RT Dose together with additional improvements. Therefore, the new version shall be called "iPlan RT".

The device incorporates conformal beams, conformal IMRT beams, circular arcs, and both static and dynamic arc treatments. Moreover, a combination of optimized dynamic arc treatments together with IMRT beams was added to the treatment modalities.

The system calculates dose using a convolution algorithm as the previous version. Alternatively, a Monte Carlo method based calculation algorithm can be used as in iPlan RT Dose (K080888). The documentation & export function facilitates printouts of all parameters and results for the creation of DICOM RT (RT Plan and RT Image) files.

Adapting existing treatment plans during fractionated radiotherapy treatments is facilitated using an elastic deformation algorithm. Existing structures are morphed from an existing treatment plan onto a new follow-up scan. If necessary, these structures can be adapted by the physician and can be used to update the current treatment plan accordingly.

## Summary of Non-Clinical Testing

The performed hazard analysis shows that all relevant hazards have been taken into consideration and the corresponding measures are effective. The Verification and Validation tests were completed according to Brainlab's procedures and show that iPlan RT

- has met its specifications,
- is substantially equivalent to the predicate devices and
- is safe and effective for its intended use.

## Summary of Clinical Testing

Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness.

## Conclusion

The detailed comparison table (see "Experiences from previous product") shows substantial equivalence to the compared predicated devices.

iPlan RT 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 devices iPlan RT Image (K080886) and iPlan RT Dose (K080888).

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
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GERMANY

MAR 16 2011

Re: K103246
Trade/Device Name: iPlan RT
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: February 11, 2011
Received: February 14, 2011

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,

Mary S Pastel

Mary S. Pastel, Sc.D.
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): K103246

Device Name: iPlan RT

Indications For Use:

iPlan RT is a radiation treatment planning system that is intended for use in stereotactic, conformal, computer planned, Linac based radiation treatment of cranial, head and neck, and extracranial lesions.

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103246

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)