K053584

JUL 12 2006

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

Manufacturer

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Contact Person	Mr. Rainer Birkenbach
Summary Date	December 21, 2005

Device Name

Device Name	iPlan RT Dose
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

BrainSCAN (K994413)

Intended Use

iPlan RT Dose is a stereotactic 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 Dose 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 device BrainSCAN (K994413). 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.

iPlan RT Dose incorporates most capabilities of the predicate device BrainSCAN. The device incorporates conformal beams, conformal IMRT beams, both static and dynamic arc treatments. The system calculates dose using a convolution algorithm similar to the predicate device BrainSCAN. The documentation & export allows producing printouts of all parameters and results for the creation of DICOM RT (RT Plan and RT Image) files.

Substantial Equivalence

iPlan RT Dose 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 BrainSCAN (K994413).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 12 2006

Mr. Rainer Birkenbach
Executive Vice President
BrainLAB AG
Ammerthalstraβe 8, 85551 Heimstetten
GEMANY

Re: K053584
Trade/Device Name: iPlan RT Dose
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: June 14, 2006
Received: June 16, 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 (Premarket Approval), 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053584

Device Name: **iPlan RT Dose**

Indications For Use:

iPlan RT Dose is a stereotactic 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 Reproductive, **Abdominal,**
and Radiological **Devices**
510(k) **Number** K053584

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)