K991237

AUG 30 1999

510(k) Summary of Safety and Effectiveness
for
XPlan-2 and the HNL

1. SPONSOR

Radionics Software Applications, Inc.
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Contact Person: Nancy MacDonald, Senior Regulatory Engineer
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Date Prepared: April 7, 1999

2. DEVICE NAME

Proprietary Name: XPlan-2
Common/Usual Name: Stereotactic Radiation Treatment Planning System
Classification Name: X-ray Radiation Therapy System

3. PREDICATE DEVICES

Radionics Software Applications, Inc. believes that within the meaning of the Medical Device Amendments of 1976, the XPlan-2 system addressed in this premarket notification is substantially equivalent to the following medical devices:

- XPlan-1 LINAC-based Radiation Treatment Planning System, Manufactured by Radionics Software Applications, Inc., K972905.

- XKnife-4 LINAC-based Radiosurgery and Radiotherapy Treatment Planning System, Manufactured by Radionics Software Applications, Inc., K981055.

Radionics Software Applications, Inc. believes that within the meaning of the Medical Device Amendments of 1976, the Head and Neck Localizer (HNL) addressed in this premarket notification is substantially equivalent to the following medical devices:

- Gill-Thomas-Cosman (GTC) Relocatable Head Holder System, Manufactured by Radionics Software Applications, Inc., K934523 and K962155.

- Laser Angio Target Localizer (LATL), Manufactured by Radionics Software Applications, Inc., K972905.

4. DEVICE DESCRIPTION

The XPlan-2 system is a stereotactic radiation treatment planning system. The XPlan-2 system, like the XPlan-1 system, consists of treatment planning software, stereotactic hardware and extensive verification and quality assurance (QA) procedures to ensure the proper system and patient setup and the proper radiation delivery. XPlan-2 radiation treatment plans are designed with stationary or "static" radiation beams. These beams can be shaped with a range of field shaping devices, such that the shape of the radiation beam conforms to the irregular shape of the lesion. The ability to shape the radiation beam enables the user to treat irregularly shaped lesions, maximizing the radiation dose to the lesion, while minimizing the radiation dose to the surrounding normal tissue and critical structures. This premarket notification is intended to describe those additional features or modifications that have been made to the XPlan System and the new Radionics Head and Neck Localizer that is to be used with the XPlan-2.

The XPlan-2 system is identical to the XPlan-1 system with the exception of the additional and modified features listed below:

- The optional use of the Joint Center for Radiation Therapy (JCRT) Primary

Plus (+) Scatter Dose Model has been added.

- A Site-Specific CT Intensity option was added to the depth calculation to account for differences in the reported intensity between various CT scanners, by using a set of fit parameters which describe the CT intensity vs. electron density curve.

- Support for the export of ASCII files that are readable by the industry standard IMPAC Record and Verify system has been added.

- The Dose-Volume Histogram (DVH) Sampling Function has been modified from a spherical sampling plan to a more uniform sampling plan.

- The Surface Dose Calculation has been modified to update the surface dose display when the surface dose dial is changed.

- The Plan Manager Module has been added to enable the user to easily save, restore or delete filed patient plans and standard plans via a browser.

- The Patient Treatment Volume (PTV) and Digitally Reconstructed Radiograph (DRR) Modules have been modified to support Secondary Data Sets (e.g., MR or CT2).

- Support for the new Radionics Head and Neck Localizer (HNL) has also been added to the XPlan-2 System.

5. INTENDED USE

XPlan-2 is a stereotactic radiation treatment planning system with the same intended use as the commercially available XPlan-1 system. XPlan-2 is intended for use in stereotactic, conformal, computer planned, LINAC (linear accelerator) based radiation treatment.

The Head and Neck Localizer (HNL) has the same intended use as the commercially available Radionics Gill-Thomas-Cosman (GTC) Relocatable Head Holder System and LATL Localizer. The HNL is intended to immobilize the patient during the acquisition of images taken for treatment planning, and to immobilize and relocalize the patient during radiation therapy treatments sessions or fractions.

6. GENERAL SAFETY AND EFFECTIVENESS

The device labeling contains instructions for use. It includes indications for use, cautions, warnings and user quality assurance procedures. The training and installation sessions provide assurance that the user understands all aspects of the

XPlan-2 System; mechanical, computer and software, plus its intended functionality. This information promotes safe and effective use of the device.

7. Comparison of Technological Characteristics

Radionics Software Applications, Inc. believes that the information and testing provided in this submission clearly describes the technological characteristics of the XPlan modifications and additional features and demonstrates that XPlan-2 is substantially equivalent to the commercially available XPlan-1 and XKnife-4 systems.

8. Performance Testing

The design of the XPlan-2 system, including the use of the HNL, has been thoroughly validated at the unit and system level. Nonclinical tests were conducted to demonstrate that XPlan-2 software meets all product requirements. This testing also demonstrates that the performance is substantially equivalent to the predicate devices cited above.

9. Head and Neck Localizer (HNL)

A summary of the information contained in this premarket notification that addresses safety and effectiveness follows:

9.1 Safety Summary

The HNL system has quality assurance equipment and procedures to verify, prior to patient treatment, that the HNL is accurately positioned with respect to the patient's head and neck. Device testing confirms that the accuracy of repeat positioning with the HNL is ±3 mm in the head and neck region.

9.2 General Safety and Effectiveness Concerns

The HNL labeling contains instructions for use. The HNL Operator's Manual includes indications for use, cautions, warnings and user quality assurance procedures. This information promotes safe and effective use of the device.

9.3 Description of Device and Basis for Substantial Equivalence

The HNL system, addressed in the premarket notification, has the same intended use and technological characteristics as the commercially available Radionics Software Applications, Inc. GTC Relocatable Head Holder System and the LATL system. Like the GTC, the HNL is non-invasive, and allows repeat positioning for lower dose multiple fractionated radiosurgery treatments. Like the LATL, the HNL is used as a method for achieving target positioning at isocenter prior to patient treatment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 30 1999

Nancy C. MacDonald
Sr. Regulatory Engineer
Radionics, Inc.
22 Terry Avenue
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Re; K991237
Xplan-2 Stereotactic RTP System
Dated: April 7, 1999
Received: April 12, 1999
Regulatory Class: II
21 CFR 892.5050/Procode: 90 MUJ

Dear Ms. MacDonald:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991237

Device Name: XPlan-2 Stereotactic Radiation Treatment Planning System

Indications For Use:

XPlan-2 is a stereotactic LINAC-based radiation treatment planning system. XPlan-2 localizes lesions to be treated using CT scans, MR scans, and digitized angiographic film. XPlan-2 provides a stereotactic planning system for treatment of tumors at sites such as cranial, base of skull, head and neck. The conformal stereotactic radiation therapy treatments are delivered over multiple fractions.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segmm

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991237

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)