

Summary of Safety and Effectiveness

K972905

OCT 28 1997

General Information

Classification:	Class II
Common Name:	Stereotactic Radiation Treatment Planning System
Device Trade Name:	XPlan-1
Intended Uses:	Computer planned LINAC-based stereotactic radiotherapy procedures
Predicate Device:	RSA XKnife-3 System and CMS Focus System
Establishment Name and Address:	Radionics Software Applications, Inc. 22 Terry Avenue Burlington, MA 01803
Contact Name and Phone:	Renee J. Thibeault or Linda Jalbert, (617) 272-1233
Establishment Registration Number:	1222895
Performance Standard:	None established under Section 514

Substantial Equivalence Determination

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

Safety Summary

RSA XPlan-1 system testing verifies that the beam shaping function generated the correct aperture and that the dose displays in the Geometry Viewer and Dose Summary are correct. Further, it verifies that the PTV generation, Block and MLC generation, DRR display and other new features are accurate.

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-1 System; mechanical, computer and software, plus its intended functionality. This information promotes safe and effective use of the device.

Description of the Device and the Basis for Substantial Equivalence

The XPlan-1 system has the same intended use and similar technological characteristics as the commercially available XKnife-3 Stereotactic Radiation Treatment Planning System. Like XKnife-3, the XPlan-1 system includes the same image acquisition, localizing, contouring and beam planning techniques. In addition, XPlan-1 and XKnife-3 both contain methods of QA verification for targeting setup and delivery. XPlan-1 includes modifications of the XKnife-3 system, such as the ability to use conformal collimation devices and a modification to the dose algorithm to account for the use of conformal collimation devices. XPlan-1 also supports the use of the Laser Angio Target Localizer (LATL) as an additional QA check to verify the orientation and position of the LINAC jaws and gantry, the collimator and couch rotation. Like the XKnife-3 use of the Rectilinear Phantom Pointer (RLPP) and Laser Target Localizer Frame (LTLF), XPlan-1 supports the use of the LATL to confirm system alignment at isocenter and to position the patient at isocenter.

XPlan-1 is also substantially equivalent to the commercially available Conformal Radiation Treatment Planning System, FOCUS. Like FOCUS, XPlan-1 supports the use of LINAC jaws, MLCs and wedges to modify the shape and attenuation of the beam. Both

XPlan-1 and FOCUS also have the ability to model the total dose of radiation to the target volume and surrounding tissue via a 3D Beam's Eye View and 2D beam visualization. Both systems, also have the ability to display dose in a point, plane or volume display, in addition to the dose-volume histogram.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Renee J. Thibeault
Radionics Software Applicants, Inc.
22 Terry Avenue
Burlington, MA 01803-2516

Re: K972905
Xplan-1 Stereotactic Radiation Treatment Planning System
Dated: August 5, 1997
Received: August 6, 1997
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

OCT 28 1997

Dear Ms. Thibeault:

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 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 requirement, 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/dsmmain.html>.

Sincerely yours,

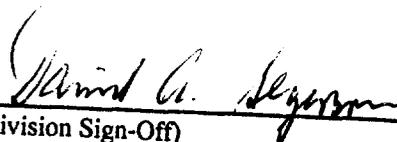
Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

The following are the indications for use of the XPlan-1 system:

XPlan-1 is a stereotactic LINAC-based radiation treatment planning system. XPlan-1 localizes lesions to be treated using CT scans, MR scans and digitized angiographic film. XPlan-1 provides a stereotactic planning system, for treatment of tumors < 7 cm in diameter at sites such as cranial, base of skull and head. The conformal stereotactic radiation therapy treatments are delivered over multiple fractions.



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K9129105

Prescription Use _____
(Per 21 CFR 801.109)