MAY 1 8 1998

K980584

Appendix A: Summary of Safety and Effectiveness

General Information

Classification:	Class II
Common Name:	Image Correlation System
Device Trade Name:	AtlasPlan
Intended Use:	AtlasPlan is intended to be used for pre- and intra-operative planning of stereotactic procedures. This software module correlates a patient's anatomy (obtained from CT or MRI scans) with an anatomical atlas of the brain. AtlasPlan may be used alone or in conjunction with neurosurgery, radiotherapy, and radiosurgery planning systems.
Predicate Device:	Medical Instrumentation and Diagnostics Corporation (MIDCO) cass System (#K894263A, 9/1/89; #K911750, 10/15/91; #K921740, 4/7/93)
Establishment Name and Address:	Radionics Software Applications, Inc. 22 Terry Avenue Burlington, MA 01803
Contact Name and Phone	Nichole Riek, (781) 272-1233
Date Summary was prepared	February 13, 1998
Establishment Registration Number:	1222895
Performance Standards:	None established under Section 514

Substantial Equivalence Determination

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

Description of the Device and Basis for Substantial Equivalence

AtlasPlan is a stereotactic planning tool which gives the clinician access to a digitized atlas of the brain. The AtlasPlan system, addressed in this premarket notification, has the same intended use and technological characteristics as the commercially available MIDCO cass System. Like the cass System, AtlasPlan utilizes a workstation to compare patient scans (CT or MRI) with a digitized stereotactic atlas. In addition, both systems allow the user to view entry and target points and labels for anatomical structures. Both systems output BRW coordinates for use in further procedure planning.

Appendix A: Summary of Safety and Effectiveness
(Continued)

Safety Summary

The RSA AtlasPlan system/unit testing rigorously tests the features of the software. The results of the testing indicate that AtlasPlan is safe and reliable for its intended use.

General Safety and Effectiveness Concerns

The device labeling contains a User's Manual which includes indications for use, cautions and warnings, as well as the general operating instructions required for proper use of the device. In addition, thorough training and support is provided to clinics that acquire and use AtlasPlan. This information promotes safe and effective use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 1998

Ms. Nichole Riek
Regulatory Engineer
Radionics Software Applications, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803-2516

Re: K980584
Trade Name: Atlas Plan™
Regulatory Class: II
Product Code: HAW
Dated: February 11, 1998
Received: February 17, 1998

Dear Ms. Riek:

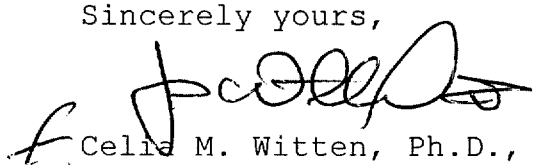
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section II: Indications for Use

Indications for Use:

AtlasPlan is intended to be used for pre- and intra-operative planning of stereotactic procedures. This software module correlates a patient's anatomy (obtained from CT or MRI scans) with an anatomical atlas of the brain. AtlasPlan may be used alone or in conjunction with neurosurgery, radiotherapy, and radiosurgery planning systems.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980584