Appendix 1

JUN - 3 1997

Summary of Safety and Effectiveness

General Information

Classification:	Class II
Common Name:	Surgical Planning and Guidance System
Device Trade Name:	Optical Tracking System (OTS)
Intended Uses:	The Optical Tracking System (OTS) is a graphical planning tool that allows for pre-operative and operative planning of surgical procedures. The OTS is indicated for use in surgical procedures in which anatomical landmarks are not clearly visible or where a desired target is close to critical structures.
Predicate Devices:	Radionics Operating Arm System, K951262 and K961844; StealthStation Stereotactic System, manufactured by Surgical Navigation Technologies, Inc., K954276.
Establishment Name and Address:	Radionics Software Applications, Inc. 22 Terry Avenue Burlington, MA 01803
Contact Name and Phone:	Amy J. LaForte, PhD, (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.

Description of the Device and Basis for Substantial Equivalence

The Optical Tracking System (OTS), addressed in this premarket notification, has the same intended use and similar technological characteristics as the commercially available Radionics Operating Arm System and the StealthStation Stereotactic System. The OTS is a modification of the Operating Arm System but substitutes a camera array for the operating arm to track the position of probes and various tools. This is the same camera

array utilized by StealthStation. The OTS provides an interactive, image-guided means of localizing targets in surgical procedures. In addition to the camera array, the OTS consists of a computer workstation, application software, and probes. Upon calibration of the system in the surgical environment, the surgeon selects points on the patient using a probe which are interpreted by the computer and related to corresponding points on the image.

Safety Summary

RSA Optical Tracking System (OTS) systems testing verifies that the stereotactic CT and MR localizer transformation equations are correctly encoded into the application software. Further, it verifies that all target coordinate input and displays are accurate. The results from the OTS are compared to a phantom with targets of known position. The camera array is accurate to a mean value of 0.3 mm. This accuracy is maintained over a period of extended operation.

General Safety and Effectiveness Concerns

The device labeling contains instructions for use. It includes indications for use, cautions, warnings and user quality assurance procedures. The training and installation sessions ensure that the user understands all aspects of the Optical Tracking System: hardware, computer, and software and its intended functionality. 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

JUN - 3 1997

Amy J. LaForte, Ph.D.
Senior Regulatory Engineer
Radionics Software Applications, Inc.
P.O. Box 358
22 Terry Avenue
Burlington, Massachusetts 01803-0658

Re: K964801
Trade Name: Optical Tracking System
Regulatory Class: II
Product Code: 84HAW
Dated: March 3, 1997
Received: March 4, 1997

Dear Dr. LaForte:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K96 4801

Device Name: Optical Tracking System 510(k) Submission

Indications for Use

The following is the indications for use of the OTS :

The Optical Tracking System (OTS) is a graphical planning tool that allows for pre-operative and operative planning of surgical procedures. The OTS is indicated for use in surgical procedures in which anatomical landmarks are not clearly visible or where a desired target is close to critical structures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number k964801

Prescription Use ✓ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)