K983669

NOV 18 1998

Optical Tracking System with Surface Matching Module 510(k)

Appendix A: Summary of Safety and Effectiveness

General Information

Classification:	Class II
Common Name:	Optical Frameless Planning System
Device Trade Name:	OTS with Surface Matching Module
Intended Use:	The Optical Tracking System (OTS) with Surface Matching Module is a graphical planning tool that allows for pre-operative and operative planning of cranial and spinal surgical procedures. The OTS with Surface Matching Module is indicated for use in cranial and spinal surgical procedures in which anatomical landmarks are not clearly visible or where a desired target is close to critical structures.
Predicate Devices:	Radionics Optical Tracking System (#K974602) Stealth Station Image-Guided Surgery System (K954276) with SurfaceMerge Registration option
Establishment Name and Address:	Radionics Software Applications, Inc. 22 Terry Avenue Burlington, MA 01803
Contact Name and Phone	David Cromwick, (781) 272-1233
Date Summary was prepared	October 2, 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

The OTS with Surface Matching Module is a graphical planning tool that allows for pre-operative and operative planning of cranial and spinal surgical procedures. The Surface Matching Module offers an alternate method of registering the patient to their scans. The OTS with Surface Matching Module, addressed in this premarket notification, has the same intended use and technological characteristics as the commercially available OTS, and Stealth Station Image-Guided Surgery System with SurfaceMerge registration option. Like the commercially available OTS, the OTS with Surface Matching Module offers the following functionality:

- Ability to plan frameless stereotactic surgical procedures from scanned images;
- Ability to plan stereotactic procedures performed with a Radionics CRW framed system;
- Display of image slices in 3D reconstructed space;
- Ability to display probe tip position in 2D and 3D displays;
- Ability to display "real-time" position of the probe in 2D image space;

Appendix A: Summary of Safety and Effectiveness

Description of the Device and Basis for Substantial Equivalence *(Continued)*

- Ability to reconstruct oblique slices;
- Use of Pointer (probe) as a Mouse to operate program.

Safety Summary

The RSA Surface Matching system testing rigorously tests the features of the software. The results of the testing indicate that the OTS with Surface Matching Module is safe and reliable for its intended use.

General Safety and Effectiveness Concerns

The device labeling contains Instructions for Use which include 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 the OTS. 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

NOV 18 1998

Mr. David Cromwick
Radionics, Inc.
Director of Regulatory Affairs and Quality Assurance
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K983669
Trade Name: Optical Tracking System With Surface Matching Module, Model OTS
Regulatory Class: II
Product Code: HAW
Dated: October 12, 1998
Received: October 19, 1998

Dear Mr. Cromwick:

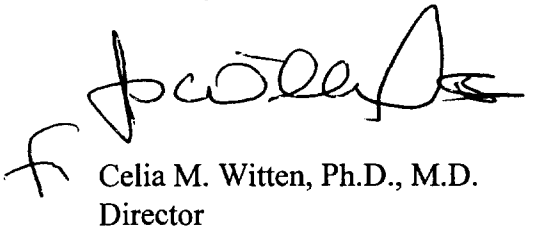
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,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

Optical Tracking System with Surface Matching Module
510(k)

Section II: Indications for Use

Indications for Use:

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

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983669