

Appendix 1**Summary of Safety and Effectiveness**

K974602

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 Optical Tracking System (K964801)
Surgical Navigation Technologies StealthStation Stereotactic System (K954276).

Establishment Name and Address: Radionics Software Applications, Inc.
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Phone (781) 272-1233
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Contact Name and Phone: Lisa Misterka Benati
(781) 272-1233

Date Summary was Prepared: December 8, 1997

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) provides an interactive, image-guided means of localizing targets in surgical procedures. A camera array tracks the position of probes and various tools. In addition to the camera array, the OTS consists of a computer workstation, application software, and probes. Upon registration 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.

The OTS with cranial and spinal applications, addressed in this premarket notification, has the same intended use and similar technological characteristics as the commercially available Radionics OTS and the Surgical Navigation Technologies StealthStation Stereotactic System. The OTS with cranial and spinal applications retains the complete functionality of the commercially available OTS while incorporating the following modifications: a new version of OAS/OTS base application software written in a new software architecture, and a new add-on software module and spinal Dynamic Reference Frame to support spinal applications. Like the OTS with cranial and spinal applications, the StealthStation Stereotactic System supports both cranial and spinal applications.

Safety Summary

RSA Optical Tracking System (OTS) system and unit testing rigorously tests the functionality of the application software. The testing verifies the capabilities of the software to match and map markers on both the patient scan and the patient. The testing also verifies that the stereotactic CT and MR localizer transformation equations are correctly encoded into the application software. Further, the testing verifies the spatial accuracy of the digitizer, as well as the accuracy of the transformations which translate points from image space to screen space and screen space to image space.

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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1998

Ms. Lisa Misterka Benati
Senior Regulatory Engineer
Radionics Software Applications, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803-2516

Re: K974602
Trade Name: Optical Tracking System
Regulatory Class: II
Product Code: HAW
Dated: March 10, 1998
Received: March 12, 1998

Dear Ms. Benati:

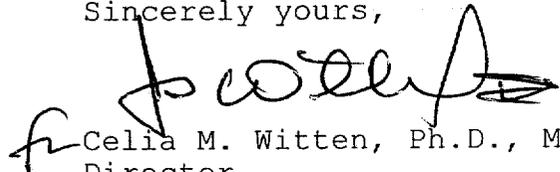
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

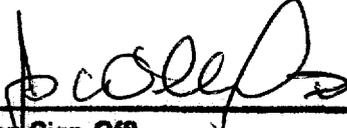
Enclosure

Indications for Use

The following are 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 cranial and spinal surgical procedures. The OTS 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.

Prescription Use X
(Per 21 CFR 801.109)



(Division Sign-Off)

Division of General Restorative Devices
510(k) Number _____

 K974602