

5.0 510(k) Summary.

K98/213

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. § 807.92.

1. The submitter of this premarket notification is:

Lisa Misterka Benati
Senior Regulatory Engineer
Radionics Software Applications, Inc.
22 Terry Avenue
Burlington, MA01803
Tel: (781) 272 - 1233
Fax: (781) 272 - 2428

This summary was prepared on April 1, 1998.

2. The names of these devices are the Radionics Universal Instrument Registration and Microscope Module I accessories for use with Radionics Optical Tracking System (OTS). The common name is Intraoperative Guidance Device, and its classification name is Stereotaxic instrument (accessory)

3. The above modular product groups are substantially equivalent to the Zeiss Surgical Microscope Navigator (SMN) and Surgical Tool Navigator (STN) modular product groups manufactured by Carl Zeiss, Inc

4. The above modular product groups consist of a registration device, LED array hardware, and operational software. When coupled with the OTS workstation, the devices allow for preoperative and operative planning of surgical procedures through workstation images.

5. The accessories are intended as a visualization aid to surgery. When fitted to a surgical instrument, the LED array hardware allows the surgeon to correlate the instrument location to the patient scan data. Likewise, when attached to a microscope, the LED array hardware allows the surgeon to correlate the focused viewing area to patient scan data, and to guide the microscope to a desired target using workstation images.

6. The technological characteristics are the same or similar to those found with the predicate device where LED systems are used to provide tracking information as an aid to surgery.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 1998

Ms. Lisa M. Benati
•Senior Regulatory Engineer
Radionics Software Applications, Inc.
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K981213
Trade Name: Universal Instrument Registration (UIS) Microscope Module I
Regulatory Class: II
Product Code: HAW
Dated: April 1, 1998
Received: April 2, 1998

Dear Ms. Benati:

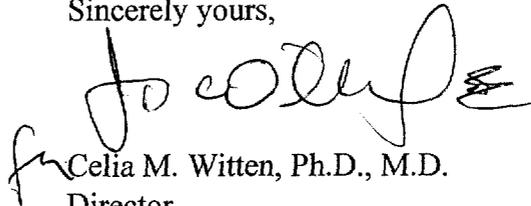
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and a long horizontal stroke extending to the right.

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

510(k) Number (if known): 981213

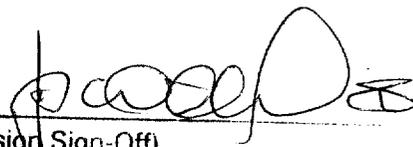
Device Name: UNIVERSAL INSTRUMENT REGISTRATION AND MICROSCOPE MODULE I
ACCESSORIES TO RADIONICS' OPTICAL TRACKING SYSTEM (OTS).

Indications For Use:

The system accessories are indicated for all cranial and spinal surgical procedures covered by the OTS where 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)



(Division Sign-Off)

Division of General Restorations

510(k) Number 981213

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use