

5.0 510(k) Summary

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.  
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Burlington, MA 01803  
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This summary was prepared on April 30, 1998.

2. The name of this device is the "Slice Editor" utility. It is an upgraded version of software intended for use in with surgical and treatment planning systems where a graphical editing facility is used to create and modify anatomical structures. The common name is image editing software and its classification name is Stereotaxic instrument (accessory/utility).

3. The Slice Editor software is substantially equivalent to the IMEX software used in Radionics' XPlan-1 for radiology applications (K972905) and its StereoPlan used for neurology applications (K946252).

4. The Slice Editor software is totally compatible with IMEX in its applications. When installed, Slice Editor provides the same anatomical data to the workstation as previously supplied with IMEX.

5. The Slice Editor is intended to serve as an image manipulation and contouring package for use with existing and new RSA applications. There is no change to indications for use.

6. The technological characteristics are the same or similar to those found with the predicate devices where contouring sessions generate anatomical data to assist in the treatment planning process.



OCT - 9 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Lisa Misterka Benati  
Senior Regulatory Engineer  
Radionics® Software Applications, Inc.  
22 Terry Avenue  
Burlington, MA 01803Re: K981597  
Slice Editor Imaging Software Utility  
Dated: August 14, 1998  
Received: August 17, 1998  
Regulatory class: II  
21 CFR 892.5050/Procode: 90 IYE

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 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) 594-4613. 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,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K981597

Device Name: Slice Editor Imaging Software Utility

**Indications For Use:**

The Slice Editor Imaging Software Utility is an image manipulation and contouring software package for use in surgical and treatment planning. The Slice Editor can replace the IMEX contouring utility as the component for contouring anatomies in all applications in which IMEX is currently utilized.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

*Samuel G. Johnson*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K981597