FEB 8 1999

K990071

ImageFusion 2.0 510(k) Summary

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

Submitter of Premarket Notification:

Nancy MacDonald
Sr. Regulatory Engineer
Radionics Software Applications, Inc.
22 Terry Ave.
Burlington, MA 01803
Telephone: (781) 272-1233, ext. 296
Fax: (781) 272-2428

Establishment Registration Number:
1222895

Performance Standards:
None established under Section 514.

This summary was prepared on January 6, 1999.

Device Name:
ImageFusion 2.0

Common Name:
Image Correlation System

Safety Summary:
Radionics Software Applications' ImageFusion 2.0 system testing verifies that the registration of MR images in stereotactic CT space is accurate and is approximately 1.7 mm on average and 2.9 mm maximum for individual landmarks. Further, system and unit testing verify that features such as bone segmentation, intensity match and landmark alignment, which form the basis of a fusion session, are accurate.

Predicate Device:
ImageFusion System: 510(k) number K960071, dated April 17, 1996.

Intended Use:
The intended use for ImageFusion 2.0 is: A pre-processing registration tool for use with other stereotactic surgical and neurosurgical treatment planning systems.

ImageFusion 2.0 510(k) Summary cont.

Device Description:
ImageFusion 2.0, aids in identification of brain tumors prior to radiotherapy or stereotactic neurosurgical treatment planning. ImageFusion 2.0 has been enhanced to allow fusion of MR/MR images, in addition to CT/CT and CT/MR fusions that the previous version was capable of performing. The fusion process is based on the matching of bone or intensity and does not rely on matching of stereotactic rods or image slices. Therefore, a non-stereotactic MR or CT image can be re-sampled according to the stereotactic coordinates of the reference CT or MR image and further used in a stereotactic capacity.

ImageFusion 2.0 is image registration software for fusing a pair of 3D image sets. Both the reference and secondary image sets can be CT or MR images. The MR scans can be T1-weighted or non T1-weighted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 8 1999

Nancy C. MacDonald
Senior Regulatory Engineer
Radionics Software Applications, Inc.
22 Terry Avenue
Burlington, MA 01803-2516

Re: K990071
ImageFusion 2.0
Dated: January 8, 1999
Received: January 11, 1999
Regulatory class: II
21 CFR 892.5050/Procode: 90 MUJ

Dear Ms. MacDonald:

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) 594-4613. 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,

Capt. Daniel G. Schultz, M.D.
Acting 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): K990071

Device Name: ImageFusion 2.0

Indications for use:

A pre-processing registration tool for use with other stereotactic surgical and neurosurgical treatment planning systems.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990071