K063230

Section 6: 510(k) Summary

Integra Radionics ImageFusion 3 510(k) Summary DEC 2 1 2006

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

1.0 The submitter of this premarket notification is:

Kevin J. O'Connell
Regulatory Affairs Manager
Integra Radionics, Inc.
22 Terry Avenue
Burlington, MA 01803
Tel.: (781) 565-1227
Fax: (781) 238-0645

This summary was prepared on October 24, 2006.

2.0 The name of the device is the Integra Radionics ImageFusion 3. The common name is System, Image Correlation and its classification name is Medical charged-particle radiation therapy system.

3.0 The above device is substantial equivalent to the Radionics ImageFusion 2, 510(k), K990071

4.0 The above system is a pre-processing registration (fusion) software for CT, MR and PET scans. The software provides QA tools for the user to evaluate the fusion results. **The results are used with other Integra Radionics applications. The software can be used on a HP UNIX or Linux workstation.**

5.0 The device like its predicates is intended for registering (fusing) stereotactic and non-stereotactic scans. The indications for use are: A pre-processing registration tool for use with other stereotactic surgical and neurosurgical treatment planning systems

6.0 The technological characteristics are the same or similar to those found with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Kevin J. O'Connell
Regulatory Affairs Manager
Integra Radionics, Inc.
22 Terry Avenue
BURLINGTON MA 01803-2516

DEC 21 2006

Re: K063230
Trade/Device Name: Integra Radionics ImageFusion 3
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: November 21, 2006
Received: November 22, 2006

Dear Mr. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063230

Device Name: Integra Radionics ImageFusion 3

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

PRESCRIPTION USE __X__ AND/OR Over-The-Counter Use _
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Hoyme

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063230