K072454

OCT 16 2007

Integra Radionics Interfix™ Patient Adapters 510(k) Summary

Submitter's Name and Address:

Integra Radionics
22 Terry Avenue
Burlington, MA 01803
781-565-1227 (Telephone)
781-238-0645 (Fax)

Contact Person and Telephone Number:

Kevin J. O'Connell
Regulatory Affairs Manager
Integra Radionics, Inc.
Tel.: (781) 565-1227

Date Summary was Prepared: August 30, 2007.

Name of the Device:

Trade Name: Integra Radionics Interfix™ Patient Adapters.

Common Name: Stereotactic Radiation Treatment Planning System and Accessories.

Classification Name: Accelerator, Linear, Medical
21 CFR 892.5050, Product Code IYE

Classification Panel: Radiology

Substantial Equivalance:

The modified device is intended for cranial fixation during CT scanning and treatment with the TomoTherapy HiArt system. Cranial fixation is within the indications for use of the predicate devices. The technological characteristics are similar to those found with the following predicate devices: LCM-2 Linac Couch-Mount System cleared via 510(k) K924632 on April 7, 1993. Knife Radiosurgery System cleared via 510(k) K912630 on November 4, 1991.

The Interfix Patient Adapters consists of two adapters, the InterFix™ CT Adapter which attaches to the CT scanner tabletop and the InterFix™ Tabletop Adapter for attachment to the TomoTherapy HiArt System tabletop. The adapters are designed to accept the Integra Radionics headrings, such as the Gill-Thomas-Cosman relocatable headring, Universal Compact Head Ring

(UCHR), Intubation Headring Assembly (HRA-IM), and Tarbell-Loeffler Cosman (TLC) Pediatric Frame.

The purpose of the Interfix system is to hold a patient securely and in the same position during the diagnostic CT scan and TomoTherapy HiArt Treatment. The adapters can be used to aid the user in aligning the patient to the lasers; however, the prescan is still required to ensure that the patient is in the correct position.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT 16 2007

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

Re: K072454
Trade/Device Name: Integra Radionics Interfix™ Patient Adapters
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: August 30, 2007
Received: August 31, 2007

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 Statement

510(k) Number (if known): K072454

Device Name: Integra Radionics Interfix™ Patient Adapters
Indications For Use:

For cranial fixation during CT scanning and treatment with the TomoTherapy HiArt System.

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

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072454