MAR - 2 2009

K083414

Radionics XKnife HDRT System 510(k) Summary

Submitter's Name and Address:

Integra Radionics
22 Terry Avenue
Burlington, MA 01803
Tel: (781) 565-1227
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Contact Person and Telephone Number:

Kevin J. O'Connell
Director Regulatory Affairs and Quality Assurance
Integra Radionics, Inc.
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Tel.: (781) 565-1227
Fax: (781) 238-0645

Date Summary was Prepared: November 17, 2008

Name of the Device:

Trade Name:	Radionics XKnife HDRT System
Common Name:	Radiation Therapy Treatment Planning System
Classification Name:	Medical charged-particle radiation therapy system Products Code 90 IYE / 90 MUJ
Classification Panel:	Radiology

Substantial Equivalence:

The Radionics XKnife HDRT System is indicated for use in radiotherapy procedures to aid in the positioning of patients immediately prior to therapy.

The technological characteristics are similar to those found in the:

Varian Medical Systems Trilogy Radio Therapy System 510(k) k081188

HDRT software is based on Integra Radionics ImageFusion 3 software (K063230) in that it compares multiple 3D images. In the case of HDRT the images compared are: the pretreatment planning image and images obtained immediately before treatment. The images immediately before treatment are obtained from Varian Trilogy Linear

Accelerators which incorporate CBCT devices capable of exporting DICOM images to shared drives. Based on the comparison of the images, HDRT specifies patient adjustment data, to insure that the patient is appropriately positioned for treatment. This functionality allows for slight errors in positioning of the patient to be compensated for, it also compensates for movement of internal organs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2009

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

Re: K083414
Trade/Device Name: Radionics XKnife HDRT System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: January 20, 2009
Received: January 21, 2009

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 (PMA), 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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting 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): K083414

Device Name: **Radionics XKnife HDRT System**

Indications For Use:

The Radionics XKnife HDRT System is indicated for use in radiotherapy procedures to aid in the positioning of patients immediately prior to therapy.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083414