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CUSA Shear Tip, an accessory of the CUSA EXcel Ultrasonic Surgical Aspirator System 510(k) Summary

Submitter's Name and Address:

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

MAY - 8 2009

Contact Person and Telephone Number:

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

Date Summary was Prepared: May 7, 2009.

Name of the Device:

Trade Name: CUSA Shear Tip

Common Name: Ultrasonic Surgical Aspirator

Classification Name: Instrument, Ultrasonic Surgical
Product Code: LFL

Classification Panel: General and Plastic Surgery

Substantial Equivalence:

The CUSA Shear Tip, an accessory of the CUSA EXcel Ultrasonic Surgical Aspirator System, is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, Plastic and Reconstructive surgery, General surgery, Orthopedic surgery, Gynecological surgery, Thoracic surgery, Laparoscopic surgery and Thoracoscopic surgery. Such functions are within the indications of use for the predicate devices. The technological characteristics are similar to those found in the following predicate devices: CUSA EXCEL Ultrasonic Surgical Aspirator System via 510(k) K981262 on July, 6, 1998; CUSA EXCEL Ultrasonic Surgical Aspirator System with Bone Tip cleared via 510(k) K051947 on August 22, 2005 and CUSA Selector NXT Ultrasonic Tissue Ablation System cleared via 510(k) K081459 on August 13, 2008.

The CUSA Shear Tip is an additional tip that is used with CUSA EXcel system to fragment fibrous tissue. The distal end of the CUSA Shear Tip has a series of opposing angled lands, instead of a flat surface. This pattern promotes refracted longitudinal waves propagating in greatly different directions at the interface to coupled tissue. No changes to the console, handpiece or suction/irrigation system were needed.

Performance testing has been completed to demonstrate that the CUSA Shear Tip can better fragment fibrous tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2009

Integra Radionics, Inc
% Mr. Kevin J O'Connell
Director Regulatory Affairs
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K090864
Trade/Device Name: CUSA Shear Tip, An Accessory of The CUSA Excel Ultrasonic Surgical Aspirator System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: LFL
Dated: May 4, 2009
Received: May 5, 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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

for Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090864

Indications for Use Statement

510(k) Number (if known): _____

Device Name: CUSA Shear Tip, an accessory of the CUSA EXcel Ultrasonic Surgical Aspirator System

Indications For Use:

The CUSA Shear Tip, an accessory of the CUSA EXcel Ultrasonic Surgical Aspirator System, is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, Plastic and Reconstructive surgery, General surgery, Orthopedic surgery, Gynecological surgery, Thoracic surgery, Laparoscopic surgery and Thoracoscopic surgery.

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 Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090864