K071669

5. 510(k) Summary

AUG 17 2007

Selector Ultrasonic Surgical Aspirator System with Bone Tip 510(k) Summary

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
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This summary was prepared on June 18, 2007.

2.0 The name of the device is the Integra Selector Ultrasonic Surgical Aspirator System with Bone Tip 510(k). The common name is Ultrasonic Surgical Aspirator and its classification name is instrument, ultrasonic surgical. The product code is LFL.

3.0 The above device is substantial equivalent to:

- Selector Integra Ultrasonic Surgical Aspirator System cleared via 510(k) K021989 on September 13, 2002.
- Radionics CUSA Excel Ultrasonic Surgical Aspirator System with Bone Tip cleared via 510(k) K051947 on August 22, 2005.
- Synergetics Sonotome Ultrasonic Aspirator Tips was cleared via the 510(k) process, K020220, on August 23, 2002.

4.0 The Selector Integra Ultrasonic Surgical Aspirator System (Selector) is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows the selective dissection of target tissue while preserving vessels, ducts and other delicate structures. The Selector consists of a console which provides control and power functions, a surgical handpiece which provides ultrasonic mechanical energy, a titanium handpiece tip and flexible irrigation flue, and a suction/irrigation system (manifold tubing and cooling water canister).

The Selector has been modified to enable it to fragment bone. This was accomplished by designing a new tip, which will be referred to as the Saber Tip, to

work with existing system. Therefore no changes to the console, handpiece or suction/irrigation system were needed.

5.0 The device like its predicates is intended for fragmentation, emulsification and aspiration of soft and hard (e.g. bone) tissue. The indications for use are: for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) 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.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2007

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

Re: K071669
Trade/Device Name: Selector Integra Ultrasonic Surgical Aspirator System with Bone Tip
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: LFL
Dated: June 18, 2007
Received: July 24, 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 (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 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 (240) 276-0115. 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071669

Device Name: Selector Integra Ultrasonic Surgical Aspirator System with Bone Tip

Indications For use: The CUSA Selector Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) 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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071669