AUG 2 3 2002

K020220

synergetics, inc.

PREMARKET NOTIFICATION
510(k) SUMMARY
[As required by 21 CFR 807.92(c)]

Prepared by: Sue Oster
Director of Quality Assurance and Regulatory Affairs

Contact Person: Same

Preparation Date: January 2, 2002

Device Name: Aspirator tips for ultrasonic surgical instrument systems

Proprietary/Trade Name: Synergetics, Inc. Sonotome™ Ultrasonic Aspirator Tips

Common/Usual Name: Ultrasonic aspirator tips

Classification Name: Instrument, Ultrasonic Surgical

The following table provides a summary of the safety and effectiveness comparison between the predicate device and the proposed device:

Name:	Predicate Device CUSA Excel Ultrasonic Surgical Aspirator	Proposed Device Synergetics Sonotome Ultrasonic Aspirator Tips	Safety & Effectiveness Comparison
Intended Use	Indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable.	Indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable.	No difference in intended use. No safety or effectiveness issues identified.
Materials and Assembly Methods	Tips made of 6AL-4V Titanium. Tips are drawn and machined from one solid piece of titanium.	Tips made of 6AL-4V Titanium. Tips are drawn and machined from one solid piece of titanium.	Identical in material and construction. No safety or effectiveness issues identified.
Packaging	Supplied non-sterile in packages of four individual tips. Also supplied in a procedural kit.	Supplied sterile in packages of three. Individual tips are supplied in a Tyvek peel pouch.	Terminal sterilization of the proposed device prior to distribution should provide greater flexibility for the surgeon to change tips during the procedure if necessary.

Synergetics Sonotome™ Ultrasonic Aspirator Tips are accessories that are attached to the handpiece of an ultrasonic surgical aspirator system manufactured by another company. The tip, which simply transmits power from the system handpiece, 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

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tissues while preserving vessels, ducts and other delicate structures. The main features on the Synergetics Sonotome™ Ultrasonic Aspirator Tips are:

- A variety of tip diameters, shapes and lengths are available for specific surgical applications.
- Curved tips are bent so as to provide clear visualization of the surgical site, unobstructed by the handpiece.
- Individually packaged, sterile tips can be replaced without the need for resterilization of the handpiece.
- Preaspiration holes in the tips minimize clogging and keep the tip clear of debris.

Validation and verification of the Ultrasonic Aspirator Tips will be accomplished through a combination of analysis and testing. This process will include a Risk Analysis and a mechanical performance test on prototype units.

The biological safety of the Ultrasonic Aspirating Tips has been assured through the selection of materials that demonstrate appropriate levels of biocompatibility. The material used (6AL-4V titanium, AMS4928) is the same as the material that is used in the predicate device and in other similar existing systems that are commercially available in the United States.

Intended Use:

Synergetics Sonotome™ Ultrasonic Aspirator Tips are intended 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
- Thoracoscopic Surgery

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2002

Synergetics, Inc.
Sue Oster
Director, Quality/Regulatory Affairs
88 Hubble Drive
St. Charles, Missouri 63304

Re: K020220
Trade/Device Name: Synergetics Sonotome™ Ultrasonic Aspirator Tips
Regulation Number: 878.4400
Regulation Name: Ultrasonic surgical instrument
Regulatory Class: Class II
Product Code: LFL
Dated: April 26, 2002
Received: August 1, 2002

Dear Ms. Oster:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K 020220/A1

510(k) NUMBER (IF KNOWN): K020220

DEVICE NAME: Ultrasonic/Straight, knife, ring curette

INDICATIONS FOR USE:

Indications for Use:

Synergetics Sonotome™ Ultrasonic Aspirator Tips are intended 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
- Thoracoscopic Surgery

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-

for Mark N Milkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020220

SK 1-7