SEP 1 3 2002

K 021989

Selector® Integra Ultrasonic Surgical Aspirator System

510(k) Summary

A. Submitter Information

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Date Prepared: June 14, 2002

B. Device Identification

Proprietary Name: Selector® Integra Ultrasonic Surgical Aspirator System
Common Name: Ultrasonic Surgical Aspirator
Classification Name: Instrument, Ultrasonic Surgical
Code: 192 LFL
Classification Panel: General and Plastic Surgery

C. Identification of Predicate Devices

The Selector® Integra Ultrasonic Surgical Aspirator System is substantially equivalent to the following previously cleared and currently marketed devices:

- CUSA Excel Ultrasonic Surgical Aspirator System (K981262)
- Sonotom 110 Ultrasonic Aspirator System (K010637)
- Sonopet UST 2001 Ultrasonic Surgical Aspirator System (K010309)

D. Intended Use

The SELECTOR® Integra Ultrasonic 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.

E. Device Description

The Selector Ultrasonic Surgical Aspirator System dissects and fragments soft tissue and leaves essential elastic structures such as nerves and blood vessels relatively undamaged. It is particularly useful for the ablation of unwanted tissue adjacent or attached to vital structures.

The system consists of a Console, which provides control and display of aspiration, irrigation and ultrasonic power, and one or more Handpieces for selective tissue removal at the surgical site. The Handpieces have a titanium tip and irrigation flue. The required settings on the console are selected by operation of up-down controls on the membrane switch front panel. The console provides power to the footswitch, which has two controls. One pedal provides proportional control of ultrasonic power, and the other the flow of irrigation fluid. An accessory Service Module may be used to provide a convenient source of suction and waste collection.

A range of Handpieces are connected to the console, both electrically and by a disposable sterile tubing kit which delivers sterile saline for irrigation, and removes aspirated waste matter. A special version of the Selector system is available for use within an MRI suite. All handpieces can be sterilized by steam autoclaving or by Ethylene Oxide. A large number of these are in routine use.

The main features of the Selector Ultrasonic Surgical Aspirator System are as follows:

- Console is compact and portable
- Simple to set up, use, clean and sterilise
- Linear action footswitch places the ultrasonic power and irrigation rate directly under the surgeon's control
- Available for use within an MRI suite
- Ergonomically designed Handpieces for ease of use
- Lightweight and compact Handpieces which are extremely energy efficient
- No external cooling system required

- Handpieces meet the tactile needs of the surgeon
- Free from external tubing, thus providing a clear view of the operating site
- Irrigation fluid is delivered directly to the surgical site allowing efficient ablation of unwanted tissue
- Variety of Handpieces specifically designed for surgery and surgeon preference, including laparoscopic
- Irrigation flue provides protection of the titanium surgical tip

F. Safety and Performance Data

The Selector Ultrasonic Surgical Aspirator System has been designed to conform with the following standards, as applicable:

CSA22.2 No. 601-1
EN 60601-1
EN60601-1-2
FCC 18
JIS T 1001/1002
UL 2601-1

The footswitch is additionally rated IPX 2.7 for dust and moisture resistance.

The Selector® Integra Handpieces have been tested and comply to ISO 10993-1 for steam sterilisation and ISO 11135:1994 for ethylene oxide sterilisation.

G. Summary of Substantial Equivalence

The Selector Ultrasonic Surgical Aspirator System (Console, Handpieces and Accessories) is substantially equivalent in function, technical specifications, performance and intended use to the following predicates:

- CUSA Excel Ultrasonic Surgical Aspirator System, frequency 23kHz and 36kHz (K981262)
- Sonotom 110 Ultrasonic Aspirator, frequency 26.5 kHz (K010637)
- Sonopet UST2001 Ultrasonic Surgical Aspirator, frequency 25 kHz/ 34kHz (K010309)

Table 1 is a feature comparison chart regarding the subject of this Premarket Notification for the SELECTOR® Integra Ultrasonic Aspirator (previously cleared to marked under 510(k)s K901974 and K925129) and the predicate devices.

Substantial Equivalence Table

TABLE 1	CUSA Excel K981262	Sonopet UST 2001 K010309	Berchtold Sonotom 110 K010637	*SELECTOR® K901974 &* K925129
▪ Indications for Use	Neuro Gastro Uro Plastic & Recon. General Ortho Gynecology Thoracic Laparoscopic Thoracoscopic	Neuro Gastro Uro Plastic & Recon. General Ortho Gynecology Thoracic Laparoscopic Thoracoscopic	Neuro Uro General Gynae	Neuro Gastro Uro Plastic & Recon. General Ortho Gynecology Thoracic Laparoscopic Thoracoscopic
• Where used	Hospitals	Hospitals	Medical environment	Hospitals
▪ Basic Operating Principle	Ultrasonic action through Titanium Alloy Tip onto biological tissue causes fragmentation and cavitation of tissue. Irrigation system bathes site, aspiration removes unwanted ablated tissue.			
▪ Vibration System	Magnetostrictive	Piezo	Piezo	Piezo
▪ Frequency	23 kHz & 36 kHz	25 kHz & 34 kHz	26.5 kHz	24 kHz & 35 kHz
▪ Irrigation Flow	1-29 cc/min	3-<10 ml/min	10-50 ml/min	0-50 ml/min
▪ Aspiration Vacuum	0-660 mmHg	0-500 mmHg	-20 to -90 kPa	0-600 mmHg
• Tip Amplitudes	Max 23 kHz:355µm Max 36 kHz:210µm	Max 350µm	Max 350µm	Max 24 kHz:305µm Max 35 kHz:215µm
• Materials in contact with tissue	TiAl6V4 Titanium Alloy	Not known	Titanium	TiAl6V4 Titanium Alloy
• Power Source	110V 60Hz	100-200V 50/60Hz	110-130V 50/60Hz or 220-260V 50/60Hz	100-240V 50/60Hz
• Sterility	Steam	Steam EtO	Steam EtO	Steam EtO
• Electrical Safety • Standards Met	IEC 601-1 601-2-2 60601-1-2 CSA 22.2	Not known	EN 60601	CSA 22.2 No. 601-1 60601-1 60601-1-2 FCC 18 JIS T1001/1002 UL2601-1
• Tip External Diameters	1.93 to 3.98 mm	Not known	3.2 to 4.5 mm	1.95 to 2.5 mm
• Handpiece Cooling	Water	Air	Air	Air

Conclusion:

Valid scientific evidence through biocompatibility physical property and performance testing provide reasonable assurance that the SELECTOR® Integra Ultrasonic Aspirator System is safe and effective under the proposed conditions of use, and is, with respect to intended use and technological characteristics, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2002

Integra Neurosciences
Nikki Robinson
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United Kingdom

Re: K021989
Trade/Device Name: Selector® Integra Ultrasonic Surgical Aspirator System
Regulation Number: 888.4580
Regulation Name: Sonic surgical instrument and accessories/attachments
Regulatory Class: Class II
Product Code: LFL
Dated: June 14, 2002
Received: June 18, 2002

Dear Ms. Robinson:

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 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

INDICATIONS FOR USE

510(K) Number: K021989

Device Name: **SELECTOR® Integra Ultrasonic Surgical Aspirator**

INDICATIONS FOR USE:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) Or Over-the-Counter Use ____ (Optional Formal 1-2-96)

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

510(k) Number 31 K021989