

DEC 16 2003

K032424 (pg 1 of 2)
510(k) Summary

LOTUS Laparoscopic Ultrasound Surgery System

Common Name: Ultrasound Surgical Instrument
Common/Classification Name: Unclassified
SRA Developments Ltd
Bremridge House
Ashburton
Devon TQ13 7JX
UK

Contact: Dr. Michael J. R. Young,
Prepared: July 31, 2003

A. LEGALLY MARKETED PREDICATE DEVICES

The **LOTUS Laparoscopic Ultrasound Surgery System** is substantially equivalent to the UltraCision Laparoscopic Coagulating Shears cleared by FDA as K980099), and to the AutoSuture Ultrasonic Surgical Instrument (K971861).

B. DEVICE DESCRIPTION

The **LOTUS (Laparoscopic Operation by Torsional UltraSound)** system consists of the power module, the reusable part of the handset, and the disposable part of the handset. The Lotus system employs torsional mode ultrasound at 36 kHz to cut and coagulate soft tissue during laparoscopic or open surgery.

C. INTENDED USE

The **LOTUS Laparoscopic Ultrasound Surgery System** is indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. LOTUS may be used as an adjunct to or substitute for electrosurgery, laser surgery, and traditional scalpels in general, gynecologic, and thoracic surgery.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **LOTUS Laparoscopic Ultrasound Surgery System** is a medical device, and it has the same indications for use and target population as the legally marketed predicate device.

The **LOTUS Laparoscopic Ultrasound Surgery System** has the same

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technological characteristics as the predicate device. However, the descriptive characteristics may not be sufficiently precise to assure substantial equivalence. Therefore, performance testing was carried out for some characteristics. The data from this testing was available and was presented in this 510(k). The data do, in fact, demonstrate equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The basic technological characteristics of the LOTUS device are the same as those of the predicate devices. The only difference is that the LOTUS is a torsional mode device, while the predicate devices are longitudinal-mode devices.

F. TESTING

Testing to electrical safety and electromagnetic compatibility standards was successfully carried out. Biocompatibility testing was conducted on some patient-contacting parts of the system. Performance testing in an animal model was conducted and performance was confirmed in an experiential clinical study.

G. CONCLUSIONS

This premarket notification has demonstrated substantial equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2003

SRA Developments, Ltd
c/o T. Whit Athey, Ph.D.
The Health Policy Resources Group, LLC
2305 Gold Mine Road, Suite 200
Brookeville, Maryland 20833-2233

Re: K032424

Trade/Device Name: LOTUS Laparoscopic Ultrasound Surgery System
Regulatory Class: Unclassified
Product Code: LFL
Dated: November 6, 2003
Received: November 6, 2003

Dear Dr. Athey:

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 (301) 594-4659. 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 (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 (if known): K032424

Device Name: LOTUS Laproscopic Ultrasound Surgery System

Indications For Use:

The LOTUS Laproscopic Ultrasound Surgery System is indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. LOTUS may be used as an adjunct to or substitute for electrosurgery, laser surgery, and traditional scalpels in general, gynecologic, and thoracic surgery.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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