

K063531

Page 1 of 3

510(k) Summary

Series 3 LOTUS Laparoscopic Ultrasound Surgery System

FEB 22 2007

Common: Ultrasound Surgical Instrument
Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories (21 C.F.R. 878.4400)
Product Code: LFL
Sponsor: SRA Developments Ltd
Bremridge
Ashburton
Devon TQ13 7JX
T: +44 1364 652426
F: +44 1364 653589

Contact: Dr. Michael J. R. Young

A. REASON FOR SUBMISSION

This 510(k) is being filed for three main reasons. Firstly, it is to cover improvements in the existing LOTUS (K032424) which includes a new generator and ergonomically improved handsets. Secondly there are new hook handsets available that were not covered in the original 510(k). Thirdly is a change to the intended use that now includes its use in orthopedic surgery.

B. LEGALLY MARKETED PREDICATE DEVICES

The SRA Developments Series 3 LOTUS Laparoscopic Ultrasound Surgery System is substantially equivalent to the LOTUS Laparoscopic Coagulation and Cutting System cleared for marketing under K032424, the Ultracision Harmonic Scalpel Blades and Shears cleared for marketing under K060245, the Ultracision 5mm Hard Sheath Laparoscopic Blade and Ultracision HS2 Blade (K971302) and Orthosonics OSCAR System for Cemented Arthroplasty Revision (K021502).

C. DEVICE DESCRIPTION

The SRA Developments Series 3 LOTUS Laparoscopic Ultrasound Surgery System consists of the power module which generates the ultrasonic energy and provides overall control of the device, the reusable part of the handset; and the disposable part of the handset. The Series 3 LOTUS system employs torsional mode ultrasound at 35-40kHz to cut and coagulate soft tissue during laparoscopic or open surgery.

D. INTENDED USE

Series 3 LOTUS shear & hook are 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, gynecological, thoracic surgery, and exposure to orthopedic structures (such as hip joint).

E. TECHNOLOGICAL CHARACTERISTICS

The Series 3 LOTUS Laparoscopic Coagulation and Cutting System has the same technological characteristics as the predicate device LOTUS Laparoscopic Coagulation and Cutting System. The only difference with the predicate device Ethicon Ultracision Harmonic Scalpel Blades and Shears is that the LOTUS is a torsional mode device whereas the harmonic scalpel is longitudinal.

F. SUBSTANTIAL EQUIVALENCE SUMMARY

The Series 3 LOTUS Laparoscopic Coagulation and Cutting System is a medical device, and it has the same indications for use and target population as the legally marketed predicate devices.

The Series 3 LOTUS Laparoscopic Coagulation and Cutting System has the same technological characteristics as the predicate devices. 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).

G. TESTING

Electromagnetic compatibility testing was successfully carried out to EN 60601-1-2 and to FCC Part 18. Electrical safety testing has been carried out in-house to EN 60601-1 and SRA Developments will have the system tested to comply with UL60601-1 including Clause 19 'Patient Auxillary Current' by UL UK Ltd. before they are marketed in the US. Biocompatibility issues were covered by the LOTUS Laparoscopic Ultrasound Surgery System (K032424) application.

Performance testing was carried out in an animal study in Portugal and the results are included in this 510(k) in **Exhibit 21**. Ex-vivo testing was also completed both in Portugal and the UK, the results of this testing is also

included in **Exhibit 21**. User trials were undertaken at a number of UK hospitals. A summary of this testing is included as **Exhibit 22**.

H. 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

SRA Developments, Ltd.
% Mr. Alan Chivers
Regulatory Affairs Manager
Bremridge House
Ashburton, South Devon,
United Kingdom TQ13 7JX

FEB 22 2007

Re: K063531

Trade/Device Name: Series 3 LOTUS Laproscopic Ultrasound Surgery System
Regulatory Class: Unclassified
Product Code: LFL
Dated: January 26, 2007
Received: February 5, 2007

Dear Mr. Chivers:

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

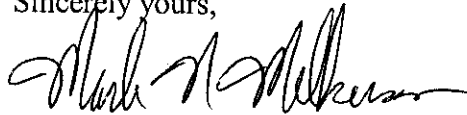
Page 2 – Mr. Alan Chivers

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

K063531

Indications for Use

510(k) Number (if known): K063531

Device Name: Series 3 LOTUS Laproscopic Ultrasound Surgery System

Indications For Use:

Series 3 LOTUS shear & hook are 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, gynecological, thoracic surgery, and exposure to orthopedic structures (such as hip joint).



Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(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

Page 1 of _____

510(k) Number K063531