DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 17, 2015

SRA Developments LTD.
Mr. Alan Chivers
Regulatory Affairs Manager
Bremridge House
Ashburton
Devon
TQ13 7JX
United Kingdom

Re: K151101
Trade/Device Name: Lotus Series 4 Ultrasonic Surgical System & Accessories
Regulatory Class: Unclassified
Product Code: LFL
Dated: June 15, 2015
Received: June 18, 2015

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K151101

Device Name: Lotus Series 4 Ultrasonic Surgical System & Accessories

Indications For Use:

Lotus Series 4 Ultrasonic Surgical System & Accessories are indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. Lotus Series 4 Ultrasonic Surgical System and Accessories 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 ✓ AND/OR (Part 21 CFR 801 Subpart D)

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)

510(k) Summary

510(k) Summary

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Date Prepared: 17th April 2015

Trade Name: Lotus Series 4 Ultrasonic Surgical System and Accessories

Common: Ultrasound Surgical Instrument

Classification Name: Unclassified

Product Code: LFL

A. REASON FOR SUBMISSION

This 510(k) is being filed to cover improvements in the existing Series 3 LOTUS Laparoscopic Ultrasound Surgery System (K063531) which includes a new generator, an additional, slimmer, waveguide blade form and ergonomically improved, single use, handpieces.

B. LEGALLY MARKETED PREDICATE DEVICES

SRA Developments Series 3 LOTUS Laparoscopic Ultrasound Surgery System cleared by FDA as K063531 on 22nd February 2007.

C. DEVICE DESCRIPTION

The SRA Developments Lotus Series 4 Ultrasonic Surgical System and Accessories consists of 3 main components - the power module which generates the ultrasonic energy and provides overall control of the device, the reusable part of the handset (Transducer and waveguide); and the disposable part of the handset (Handpiece). The Lotus Series 4 Ultrasonic Surgical System and Accessories employs torsional mode ultrasound at 35.8-36.6kHz to cut and coagulate soft tissue during laparoscopic or open surgery.

D. INDICATIONS FOR USE

The Lotus Series 4 Ultrasonic Surgical System and Accessories are indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. Lotus Series 4 Ultrasonic Surgical System and Accessories 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. PERFORMANCE BENCH TESTING

The SRA Developments design control procedures were followed to design and test the minor modifications. The testing of the new generator included the validation of the firmware and comparison of the output with the Series 3 LOTUS. To compare the outputs between the generators a Transducer was driven by each generator in turn and the amplitude at the tip of the waveguide was recorded. The results were then compared and shown to be equivalent. The new waveguide design was tested for speed of cutting and haemostasis to ensure that it was equivalent to the existing laparoscopic waveguide. The speed of cutting was tested using our standard production cutting test and the results recorded.

The results showed that the design had equivalent performance to the existing laparoscopic waveguide. Cutting and bleeding control testing using porcine tissue was undertaken using an existing laparoscopic waveguide and the new waveguide. SRA Developments have concluded that the results demonstrate equivalence between the two waveguides for cutting and bleeding control. Fatigue resistance was tested by simulating 50 surgical uses. This is the standard test given to all waveguide designs. The devices were run for 300 seconds of on time and then sterilized in an autoclave. This process was repeated 50 times and all devices remained operational for the entire period. SRA Developments have concluded that this shows equivalence between the two waveguides for fatigue resistance.

The handpiece design was tested for durability to ensure that it would survive a procedure of extreme duration. The handpieces were subjected to 600 clamping operations following which they still needed to meet the standard performance test. This test protocol was previously used to establish the durability of the Series 3 LOTUS. All devices passed the test. SRA Developments have concluded that this shows equivalence between the two handpieces for durability

The testing undertaken for the design verification and validation shows that the Lotus Series 4 Ultrasonic Surgical System and Accessories is equivalent to the predicate Series 3 LOTUS.

F. TECHNOLOGICAL CHARACTERISTICS

The basic technological characteristics of the Lotus Series 4 Ultrasonic Surgical System and Accessories are the same as those of the predicate device. Both Lotus Series 4 Ultrasonic Surgical System and Accessories and SRA Developments Series 3 LOTUS systems are designed to use torsional ultrasound at 35.8-36.6kHz to cut and seal soft tissue in endoscopic and open procedures. No change has been made to the transducers so, therefore, the energy source, materials and design remain the same. The waveguides are manufactured from the same titanium alloy (Ti 6Al/4V) in both devices. A new, slimmer waveguide variant has been added to the range for Lotus Series 4.

The patient contacting materials of the handpiece also remain the same i.e. Hastelloy, PTFE, and stainless steel. The jaw operating mechanism that utilises a rotating outer tube to drive a cam remains the same. The handpiece handle and trigger have been redesigned to be more comfortable to the user. The power level select button has been moved from the side of the handpiece to the front of the handle and the activate button has been enlarged to enable easier operation by the user.

The generator has been redesigned and now includes a single output channel, replacing the dual channels of Series 3 LOTUS. The front display has been improved to give much clearer visual feedback to the user. The digital control system and digital frequency control remain the same as does the output power at 50W.

The system can still be operated by either a foot switch or finger switches except for the Double Blade, previously called the Double Hook, that remains as foot switch activation only.

G. SUBSTANTIAL EQUIVALENCE SUMMARY

Lotus Series 4 Ultrasonic Surgical System and Accessories uses the same transducers in the same torsional mode, at the same frequency and has the same intended use as the predicate device. No new questions of safety and effectiveness are raised.

Testing shows that the addition to the waveguide range of a new, slimmer, tip design does not adversely affect the hemostatic capability of the devices.

The modification to a more ergonomic handpiece does not adversely affect the hemostatic capability of the devices.

Testing shows that the output from the transducers were similar whether driven by a Series 3 or Lotus Series 4 generator.

H. BIOCOMPATIBILITY

All Lotus Series 4 Ultrasonic Surgical System and Accessories patient contacting materials remain the same as the previously cleared Series 3 LOTUS. No new biocompatibility concerns are raised.

I. STERILIZATION

The single-use Handpieces are supplied sterile in heat sealed pouches. They are sterilized using a validated EO process ensuring a SAL of 10^{-6}. Residuals have been confirmed as being within acceptable limits. The stated shelf life for these devices is 3 years.

The Transducers have not changed from SRA Developments Series 3 LOTUS systems and so the validations and instructions remain the same. No further validations were conducted on this part of the device.

J. STANDARDS TESTING

Electrical safety testing to EN 60601-1 and IEC 60601-1 by TÜV SÜD has been completed. EMC testing and output equivalence testing have been completed.

K. 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.