December 15, 2022

SRA Developments Ltd
Phillipa Frewin
Regulatory Affairs and Quality Assurance Manager
Bremridge
Ashburton, Devon TQ13 7JX
United Kingdom

Re: K221102
Trade/Device Name: LOTUS Series 4 Enhanced Shears, LOTUS Series 5
Regulatory Class: Unclassified
Product Code: LFL
Dated: October 11, 2022
Received: October 17, 2022

Dear Phillipa Frewin:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Carr -S

for Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221102

Device Name
LOTUS Series 4 Enhanced Shears
LOTUS Series 5

Indications for Use *(Describe)*

LOTUS Series 4 Enhanced Shears
LOTUS Enhanced Shears are indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. They 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).

LOTUS Series 5
The Lotus Series 5 is indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. It 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)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

Company Information:	SRA Developments Ltd Bremridge Ashburton Devon UK TQ13 7JX T: +44 1364 652426 F: +44 1364 653589
Contact:	Phillipa Frewin RAQA Manager SRA Developments Ltd Phillipa.Frewin@bowa-medical.com

Date Prepared:	28th October 2022
Trade Name:	LOTUS Series 4 Enhanced Shears LOTUS Series 5
Common:	Ultrasound Surgical Instrument
Classification Name:	Unclassified
Product Code:	LFL

A. REASON FOR SUBMISSION

This 510(k) is being filed to add 2 variants of the LOTUS Series 4 Enhanced Shears and also includes an application for an updated version of LOTUS, LOTUS Series 5

B. LEGALLY MARKETED PREDICATE DEVICES

The new LOTUS Series 4 Enhanced Shears and LOTUS Series 5 device are substantially equivalent to those registered as part of Lotus Series 4 Ultrasonic Surgical System and Accessories (K151101).

C. DEVICE DESCRIPTION

LOTUS Series 4 Enhanced Shears

The LOTUS Series 4 Enhanced Shears consist of a reusable Transducer and a Single use Handpiece and are designed to use torsional ultrasound in the 35.4-36.6kHz range to cut and coagulate soft tissue during laparoscopic, open or bariatric surgery. The 2 types of LOTUS Series 4 Enhanced Shears subject to this application are the ES4-200CT transducer (with DS4-200CD Handpiece) that is designed for use in open surgery and the ES4-500CT transducer (with DS4-500CD Handpiece) that is designed for bariatric surgery. The new LOTUS Series 4 Enhanced Shears transducers have a similar waveguide and blade form to that of the ES4-400CT that was previously cleared as part of the Lotus Series 4 Ultrasonic Surgical System and Accessories (K151101). The LOTUS Series 4 Enhanced shears use an identical transducer stack and casing and the same LG4 generator cleared as part of K151101. The Handpieces are identical in function as those cleared as part of K151101. They are identical to the DS4-200SD and DS4-500SD except that they use the same curved jaw as the DS4-400CD. All of these devices are described in detail in K151101.

All Transducers are reusable up to 50 times and the Handpieces are single use and provided sterile

LOTUS Series 5

The LOTUS Series 5 is a modification to the Lotus Series 4 Ultrasonic Surgical System and Accessories. LOTUS Series 5 consists of new Transducers and Handpieces but are driven by the same generator as in the predicate – the LG4. The Transducers and Handpieces offer the improved feature of 360° rotation, whereas the predicate has rotation limited to 240°. To facilitate this feature, it has been necessary to redesign the transducer so that it sits axially in the plane of the waveguide. It still uses torsional ultrasound in the 35.4-36.6kHz range at the waveguide blade to perform its surgical function. The output at the waveguide blade is substantially equivalent to that of the predicate. The Handpieces of LOTUS Series 5 have had the area where the transducer fits to the Handpiece altered to allow for the 360° rotation, but the outer appearance of the Handpieces remains unchanged from the predicate.

All Transducers are reusable up to 50 times and the Handpieces are single use and provided sterile

D. INTENDED USE

LOTUS Series 4 Enhanced Shears

LOTUS Enhanced Shears are indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. They 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).

LOTUS Series 5

The LOTUS Series 5 is indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. It 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

LOTUS Series 4 Enhanced Shears

The fundamental technological characteristics (i.e. design, material, chemical composition, energy source) of the LOTUS Series 4 Enhanced Shears are equivalent to the predicate.

LOTUS Series 5

The LOTUS Series 5 is the same as the predicate in that it uses the same fundamental mode of operation i.e. torsional ultrasound in the 35.4-36.6kHz range. All patient contacting materials are the same i.e. Ti 6Al/4V, Hastelloy, PTFE and stainless steel. It has the same indications for use and target population. It also uses the same generator as the predicate. The main difference between the subject and predicate devices is that the subject device allows for 360° rotation whereas the predicate was limited to 240° rotation.

F. SUBSTANTIAL EQUIVALENCE SUMMARY

LOTUS Series 4 Enhanced Shears

	Series 4 (K151101)	Enhanced Shears
Intended Use	The Lotus Series 4 Ultrasonic Surgical System	LOTUS Enhanced Shears are indicated for soft tissue

	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).	surgical incisions when bleeding control and minimal thermal injury are important. They 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).
Energy Source	Ultrasound	No Change
Ultrasound mode	Torsional mode	No Change
Axis of transducer stack	Perpendicular to waveguide	No Change
Generator	1 Channel	Uses same generator as predicate therefore no change
Control System	Digital	Uses same generator as predicate therefore no change
Frequency Control	Digital frequency control	Uses same generator as predicate therefore no change
Power Mode	Continuous	Uses same generator as predicate therefore no change
Electrical Safety	EN 60601-1 IEC 60601-1 TÜV SÜD marked	Uses same generator as predicate therefore no change
Electromagnetic Compatibility	EN 60601-1-2 FCC Part 18	Uses same generator as predicate therefore no change
Function Control	Finger switches or footswitch	No Change
Sterilization	EO for handpiece Autoclave for transducer & waveguide	No Change
Sterile Packaging	Single wrapped in heat sealed pouches	No Change

	manufactured from Tyvek 1073B and BOPA	
Handset Design	Trigger operated jaw action designed. Handset may be rotated for optimal cutting angle	No Change
Types of Probes Included	Jaw-type, double blade, Liver Resector	Jaw-type
Size of Probe Barrel	5.5mm	No Change
Biocompatibility of patient contacting materials	Hastelloy, PTFE, Titanium 6Al/4V Stainless Steel	No Change
Shears blade type	Laparoscopic shears Curved tip Laparoscopic shears slim Curved tip Open shears Straight Tip Bariatric shears Straight Tip	Open shears Curved Tip Bariatric shears Curved Tip
Liver Resector blade type	Open Liver Resector Straight Tip Laparoscopic Liver Resector Straight Tip	Not applicable
Lengths of shears waveguides	510mm, 430mm, 255mm	No Change
Lengths of Liver Resector waveguides	430mm, 255mm	No Change
Transducer/Handpiece rotation	All shears and Liver Resectors - 240°	240°
Reusable components	Transducer & Waveguide	No Change
Power levels	High, Low, Ultra-low	Uses same generator as predicate therefore no change
Prescription Device?	Yes	No Change
Frequency / Excitation of single torsional mode in the bandwidth;	35.4-36.6kHz	Uses same generator as predicate therefore no change
Lock to torsional resonance, followed by continuous tracking of the frequency;	Yes	Uses same generator as predicate therefore no change
Automatic return to last frequency if switch off-switch on;	< 2 seconds	Uses same generator as predicate therefore no change

Power into matching circuit with waveguide (un)loaded in air;	≤ 20W	Uses same generator as predicate therefore no change
Power into handset with waveguide (un)loaded in air;	≤ 10W	Uses same generator as predicate therefore no change
Tangential peak to peak displacement (including tolerance) of waveguide distal tip at 10W into matching circuit in µm;	CV3-400 Max 250 SV3-200 Max 229 SV3-500 Max 240 ES4-400CT Max 201 LR3-200 Max 158 LR3-400 Max 192 DB3-100 Max 400 DB3-400 Max 400	ES4-200CT Max 185 ES4-500CT Max 188
Tangential displacement	May vary as blade is loaded. As a load is added to the blade energy is absorbed by the resistance. This in turn naturally reduces the tangential displacement of the waveguide	No Change
Temperature of transducer back plate after 20s continuous	≤50°C	No Change
Temperature of shroud away from distal end after 20s. continuous;	≤40°C	No Change
For intermittent use over a maximum duration of;	5 hours	No Change
Duty cycle will be determined by 'applied part' temperature;	Series 4 marked as 3s on 30s off	Uses same generator as predicate therefore no change
Life in Service (disposable part, acoustics part, reusable part);	Acoustics part: All types of Transducer unit (waveguide on torsion horn, sealed inside its plastic casing with hard-wired cable and Eeprom potted plug) must survive 50-off standard (five minute on-time) uses ie. 250 minutes or 4.16 hours of on-	No Change

	time including 50-off vacuum autoclave lumened load cycles, each at 134°C for three minutes Disposable part: must survive a single (extreme duration) clinical procedure of 1200s. or 20 minutes ON-time with no observable change in performance characteristics.	
Cable length;	2.9m	No Change
Weight Handset including acoustics and disposable;	< 300g	No Change
Ergonomic (power activation);	Must be able to be used single handed. Two finger operated switches to activate and toggle between high/normal power	No Change
Fuse Type	Internal fuses only	Uses same generator as predicate therefore no change

Conclusion: In establishing substantial equivalence of the subject LOTUS Series 4 Enhanced Shears to the predicate device SRA Developments Ltd evaluated the indications for use, intended use and technological characteristics. The LOTUS Series 4 Enhanced Shears are substantially equivalent to the predicate device. They share the same intended use and equivalent technological characteristics. The subject device is as safe and effective as the predicate device.

LOTUS Series 5

	Series 4 (K151101)	LOTUS Series 5
Intended 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	The LOTUS Series 5 is indicated for soft tissue surgical incisions when bleeding control and minimal thermal injury are important. It may be used as an adjunct to or substitute for electrosurgery, laser surgery, and traditional

	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).	scalpels in general, gynecological, thoracic surgery, and exposure to orthopedic structures (such as hip joint).
Energy Source	Ultrasound	No Change
Ultrasound mode	Torsional mode	No Change
Axis of transducer stack	Perpendicular to waveguide	Axially aligned to waveguide
Generator	1 Channel	Uses same generator as predicate therefore no change
Control System	Digital	Uses same generator as predicate therefore no change
Frequency Control	Digital frequency control	Uses same generator as predicate therefore no change
Power Mode	Continuous	Uses same generator as predicate therefore no change
Electrical Safety	EN 60601-1 IEC 60601-1 TÜV SÜD marked	Uses same generator as predicate therefore no change
Electromagnetic Compatibility	EN 60601-1-2 FCC Part 18	Uses same generator as predicate therefore no change
Function Control	Finger switches or footswitch	No Change
Sterilization	EO for handpiece Autoclave for transducer & waveguide	No Change
Sterile Packaging	Single wrapped in heat sealed pouches manufactured from Tyvek 1073B and BOPA	No Change
Handset Design	Trigger operated jaw action designed. Handset may be rotated for optimal cutting angle	No Change

Types of Probes Included	Jaw-type, double blade, Liver Resector	Jaw-type, Liver Resector
Size of Probe Barrel	5.5mm	No Change
Biocompatibility of patient contacting materials	Hastelloy, PTFE, Titanium 6Al/4V Stainless Steel	No Change
Shears blade type	Laparoscopic shears Curved tip Laparoscopic shears slim Curved tip Open shears Straight Tip Bariatric shears Straight Tip	Open shears Curved Tip Laparoscopic shears Curved tip Bariatric shears Curved Tip
Liver Resector blade type	Open Liver Resector Straight Tip Laparoscopic Liver Resector Straight Tip	Open Liver Resector Straight Tip Laparoscopic Liver Resector Straight Tip
Lengths of shears waveguides	510mm, 430mm, 255mm	No Change
Lengths of Liver Resector waveguides	430mm, 255mm	No Change
Transducer/Handpiece rotation	All shears and Liver Resectors - 240°	360°
Reusable components	Transducer & Waveguide	No Change
Power levels	High, Low, Ultra-low	Uses same generator as predicate therefore no change
Prescription Device?	Yes	No Change
Frequency / Excitation of single torsional mode in the bandwidth;	35.4-36.6kHz	Uses same generator as predicate therefore no change
Lock to torsional resonance, followed by continuous tracking of the frequency;	Yes	Uses same generator as predicate therefore no change
Automatic return to last frequency if switch off-switch on;	< 2 seconds	Uses same generator as predicate therefore no change
Power into matching circuit with waveguide (un)loaded in air;	≤ 20W	Uses same generator as predicate therefore no change

Power into handset with waveguide (un)loaded in air;	≤ 10W	Uses same generator as predicate therefore no change
Tangential peak to peak displacement (including tolerance) of waveguide distal tip at 10W into matching circuit in µm;	CV3-400 Max 250 SV3-200 Max 229 SV3-500 Max 240 ES4-400CT Max 201 LR3-200 Max 158 LR3-400 Max 192 DB3-100 Max 400 DB3-400 Max 400	ES5-200CT/360° Max 158 ES5-400CT/360° Max 218 ES5-500CT/360° Max 210 LR5-200ST/360° Max 106 LR5-400ST/360° Max 94
Tangential displacement	May vary as blade is loaded. As a load is added to the blade energy is absorbed by the resistance. This in turn naturally reduces the tangential displacement of the waveguide	No Change
Temperature of transducer back plate after 20s continuous	≤50°C	No Change
Temperature of shroud away from distal end after 20s. continuous;	≤40°C	No Change
For intermittent use over a maximum duration of;	5 hours	No Change
Duty cycle will be determined by 'applied part' temperature;	Series 4 marked as 3s on 30s off	Uses same generator as predicate therefore no change
Life in Service (disposable part, acoustics part, reusable part);	Acoustics part: All types of Transducer unit (waveguide on torsion horn, sealed inside its plastic casing with hard-wired cable and Eeprom potted plug) must survive 50-off standard (five minute on-time) uses ie. 250 minutes or 4.16 hours of on-time	No Change

	including 50-off vacuum autoclave lumened load cycles, each at 134°C for three minutes Disposable part: must survive a single (extreme duration) clinical procedure of 1200s. or 20 minutes ON-time with no observable change in performance characteristics.	
Cable length;	2.9m	No Change
Weight Handset including acoustics and disposable;	< 300g	< 320g
Ergonomic (power activation);	Must be able to be used single handed. Two finger operated switches to activate and toggle between high/normal power	No Change
Fuse Type	Internal fuses only	Uses same generator as predicate therefore no change

Conclusion: In establishing substantial equivalence of the subject LOTUS Series 5 to the predicate device SRA Developments Ltd evaluated the indications for use, intended use and technological characteristics. The LOTUS Series 5 are substantially equivalent to the predicate device. They share the same intended use and equivalent technological characteristics. The subject device is as safe and effective as the predicate device.

G. TESTING

LOTUS Series 4 Enhanced Shears

LOTUS Series 4 Enhanced Shears use the same generator as the predicate and, therefore, no further Electromagnetic compatibility testing or electrical safety testing was carried out. All patient contacting materials are the same as in the predicate device and so further biocompatibility testing was not deemed necessary.

Performance testing was carried out using bench testing. Testing undertaken:

Performance testing cut times

Transducer lifetime

The results of the testing are included in this submission.

No animal testing has been undertaken.

LOTUS Series 5

All patient contacting materials are the same as in the predicate device and so further biocompatibility testing was not deemed necessary.

LOTUS Series 5 uses the same generator as the predicate.

Electrical safety leakage testing was undertaken.

Performance testing was carried out using bench testing.

Performance testing undertaken:

Acoustic performance cut times, maximum average power and frequency tracking.

Thermal spread in 3 types of tissue (muscle, kidney and liver).

Length of dissection.

Transducer lifetime of the LOTUS Series 5.

All testing showed that the LOTUS Series 5 is equivalent to the predicate.

The results of the testing are included in this submission.

No animal testing has been undertaken.

H. STERILIZATION

LOTUS Series 4 Enhanced Shears

The single-use Handpieces are supplied sterile in heat sealed pouches. As the Handpieces are made to the same design and of the same materials, use the same packaging, sealing process and parameters, and the same EO sterilization cycle at the same sub-contract sterilizing company as the devices

listed in the predicate further sterilization, residuals and ageing testing was not required. The devices have the same SAL of 10^{-6}, residuals are still within acceptable limits and the shelf life remains 3 years.

The Transducers have not changed from those listed in the predicate and so the validations remain the same. No further validations were conducted on this device.

LOTUS Series 5

The single-use Handpieces are supplied sterile in heat sealed pouches and have an SAL of 10^{-6}. The changes to the Handpiece do not present any greater challenge to the EO gas path. A study was undertaken to see whether any change in product density affected the sterilization evaluation. The overall change in density was well within limits established in the existing sterilization validation. As there were changes to some internal components, testing for residual levels will be performed prior to marketing. These tests will ensure that residuals remained within safe limits. The sterile barrier and sealing method remain the same as the predicate, however, accelerated ageing was still undertaken to ensure that the device itself would still function for the entirety of its stated lifetime.

Reprocessing validation has been performed on the new Transducers. The validated cleaning and autoclave sterilization process is included in the Instructions for Use.

I. CONCLUSION

LOTUS Series 4 Enhanced Shears

The conclusions drawn from the subject device indications for use, technological characteristics and performance testing demonstrates that the subject device is as safe and effective as, and is substantially equivalent to, the legally marketed predicate devices.

LOTUS Series 5

The conclusions drawn from the subject device indications for use, technological characteristics and performance testing demonstrates that the subject device is as safe and effective as, and is substantially equivalent to, the legally marketed predicate devices.