May 31, 20224

STERIS Corporation
Steven Elliott
Senior Manager, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060-1834

Re: K241055
Trade/Device Name: Electro Lube NXT
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 17, 2024
Received: April 17, 2024

Dear Steven Elliott:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.05.31 14:38:58 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241055

Device Name

Electro Lube NXT

Indications for Use *(Describe)*

Electro Lube NXT is a single patient use device used in open and minimally-invasive surgery to reduce tissue adhesion and eschar on electrosurgical instruments.

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.

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STERIS®

510(k) Summary
For
Electro Lube NXT

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Summary Date: May 31, 2024

STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION
Electro Lube NXT

1. Device Name

Trade Name:	Electro Lube NXT
Device Class:	Class II
Common/usual Name:	Electrosurgical Non-stick Coating Accessory
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification Number:	21 CFR 878.4400
Product Code:	GEI

2. Predicate Device

K033880 Electro Lube

Table 1. Device Comparison Table for Electro Lube NXT and Predicate

Feature	Electro Lube (Predicate Device/K033880)	Electro Lube NXT (Proposed device)	Comparison
Indications for Use	Electro Lube is a single patient use device that is intended to be used on electrodes to reduce sticking.	Electro Lube NXT is a single patient use device used in open and minimally invasive surgery to reduce tissue adhesion and eschar on electrosurgical instruments.	Similar. The Language has been revised to clarify the intended use.
Intended Use	Electro Lube is intended to be used on electrodes to reduce sticking and eschar.	Electro Lube NXT is intended to be used on electrodes to reduce sticking and eschar.	Same
Components	• Electro Lube Vial containing 4mL of Electro Lube • Foam applicator pad with adhesive backing and barium strip	• Electro Lube NXT Vial containing 4mL of Electro Lube NXT • Foam applicator pad with adhesive backing and barium strip	Same
Materials of Construction	• Electro Lube –phospholipid solution • Accessory Foam Sponge - Polyurethane Foam; Medical Double-Coated Tape; Barium Cord • Electro Lube Bottle – Polyethylene	• Electro Lube NXT - polyol ester Accessory Foam Sponge - Polyurethane Foam; Medical Double-Coated Tape; Barium Cord • Electro Lube NXT Bottle – Polyethylene	Electro Lube formulation changed. Other materials of construction are the same
Sterile	Yes - Irradiation	Yes - Irradiation	Same
SAL	10^{-6}	10^{-6}	Same
Performance	• Evaluation of Tissue Adhesion – reduced sticking of probe versus uncoated control • Evaluation of Eschar removal – reduced eschar on probe after wiping.	• Evaluation of Tissue Adhesion – reduced sticking of probe versus uncoated control • Evaluation of Eschar removal – reduced eschar on probe after wiping.	Additional testing performed to support device performance and characterize the proposed device.

Feature	Electro Lube (Predicate Device/K033880)	Electro Lube NXT (Proposed device)	Comparison
		• Evaluation of Appearance – visual inspection of color, clarity and absence of particulates. • Evaluation of Product Odor Profile – odor profile of ELII no worse than Electro Lube • Evaluation of Product Viscosity and Coating – coat electrode without excessive dripping. • Evaluation of Cutting Force and Impedance – cutting force is no greater in ELII coated electrodes vs uncoated. • Evaluation of Ease of Product Removal – Comparison of removal of ELII verses predicate by wiping. • Evaluation of Potential for the Evolution of Hazardous Scenario – observation of ignition potential of substrate using highest energy setting for successive burns • Flash Point - Closed Cup Method – Demonstration that ELII has flash point greater than 200 °C. • Evaluation of Pourability/ Dispensing – Comparison in pourability to Predicate. • Thermal Spread Evaluation - Comparison of thermal spread profiles between ELII, and uncoated electrode. • Evaluation of Sponge Interaction – determination that no damage or degradation occurs during use-life and conditions. Reprocessing Validation Test – Demonstration of effective cleaning of electrosurgical instruments after simulated use with Electro Lube NXT	
Biocompatibility	• Acute Systemic Toxicity • Dermal Sensitization • Intracutaneous Reactivity	• Acute Systemic Toxicity • Dermal Sensitization • Intracutaneous Reactivity • In Vitro Cytotoxicity • Rabbit Pyrogenicity Hemolysis	Additional tests performed to meet current biocompatibility test expectations

The proposed device is similar to the predicate devices in terms of intended use and mode of operation. The proposed device and predicate device contain differences in

indications for use to clarify the function of the proposed device. The proposed device and predicate differ in materials of construction as a new formulation is used for the proposed device. The proposed device, like the predicate device is a viscous liquid in a polyethylene vial with a foam applicator sponge. The proposed device is applied and used in the same manner as the predicate. The proposed device differs in the formulation of the non-stick agent.

3. Description of Device

Electro Lube NXT is a single-use sterile electrosurgical accessory device intended to be used on electrosurgical electrodes to prevent sticking. It is intended to be used by professional practitioners of electrosurgery in clinical environments where electrosurgery is performed.

Electro Lube NXT is sterilized by irradiation and provided to the end user in an individual sterile barrier package with one bottle containing 4mL of the anti-stick solution and one foam pad for application of the solution during use included in each pack. The foam pad includes an adhesive backing and barium filament strand of material for radiopacity.

4. Intended Use/Indications for Use

Electro Lube NXT is a single patient use device used in open and minimally invasive surgery to reduce tissue adhesion and eschar on electrosurgical instruments.

5. Summary of Nonclinical Tests

Electro Lube NXT has the same intended use and technological characteristics that do not raise different questions of safety and effectiveness as compared to the predicate device. Testing to assess and demonstrate substantial equivalence to the predicate is summarized below.

Test	Criterion	Conclusion
Evaluation of Appearance	The material is clear and homogenous without any particulate	Pass
Evaluation of Product Odor Profile	odor profile of Electro Lube NXT is equivalent or better than the odor profile of the predicate	Pass
Evaluation of Product Viscosity and Coating	The material visually coats the electrode as well or superior to the coating applied by the predicate and that Electro Lube NXT does not drip more frequently than the predicate.	Pass

Test	Criterion	Conclusion
Evaluation of Cutting Force and Impedance	the cutting force required for an electrode coated in Electro Lube NXT is not more than the cutting force required for a bare electrode.	Pass
Evaluation of Electrode Adherence to Tissue	no greater weight loss when an electrode coated in Electro Lube NXT is removed from the tissue as compared to that which occurs when the bare electrode is removed from tissue	Pass
Evaluation of Ease of Product Removal	Percentage of product removed by wiping is higher or not statistically different from the predicate device removal	Pass
Evaluation of Ease of Eschar Removal	Percentage of eschar removal after tissue burns using a blade electrode is with product is higher or not significantly different from the eschar removed from an uncoated blade	Pass
Evaluation of Potential for the Evolution of Hazardous Scenario	No observance of hazardous situations (fire, ESU fault) resulting from repeated use of product to cut tissue	Pass
Flash Point Determination- Closed Cup Method	Flashpoint greater that 200°F	Pass
Evaluation of Pourability/Dispensing	Pourability equivalent or better than predicate.	Pass
Evaluation of Sponge Interaction	Applicator sponge incorporates product, does not become discolored, exhibits no damage and does not leave particulate on electrosurgical instruments	Pass
Reprocessing Validation Testing	Use of product does not prevent cleaning of electrosurgical instruments to accepted thresholds	Pass
Thermal Spread Evaluation	Thermal damage associated with the tested electrosurgery tools (irrigating bipolar forceps and blade electrodes) were not negatively impacted by the use of Electro Lube NXT	Pass
Biocompatibility	Cytotoxicity – *MEM Elution*	Pass
	Sensitization – *Skin Sensitization Study in Guinea Pigs by Guinea Pig Maximization Test*	Pass
	Irritation – *EL201 Intracutaneous Reactivity Test in New Zealand White Rabbits*	Pass
	Acute Systemic Toxicity – *Acute Systemic Toxicity Test in Wistar Rats*	Pass
	Hemocompatibility – *ASTM Hemolysis Direct Contact and Extract Methods*	Pass
	Pyrogenicity – *Material Mediated Pyrogenicity Test in New Zealand White Rabbits*	Pass

6. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the proposed device is as safe, as effective and performs at least as well as the legally marketed predicate device K033880, Class II (21 CFR 878.4400), product code GEI.