



September 24, 2026

Karl Storz SE & CO. KG
Mario Trujillo
Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245-5017

Re: K254303
Trade/Device Name: KARL STORZ SUPRALOOP
Regulation Number: 21 CFR§ 884.4160
Regulation Name: Unipolar Endoscopic Coagulator-Cutter and Accessories
Regulatory Class: II
Product Code: KNF
Dated: August 25, 2026
Received: August 25, 2026

Dear Mario Trujillo:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

JASON ROBERTS -S

Jason R. Roberts, Ph.D.

Assistant Director

DHT3B: Division of Reproductive,

Gynecology, and Urology Devices

OHT3: Office of Gastrorenal, ObGyn,

General Hospital, and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K254303

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Please provide the device trade name(s).

?

KARL STORZ SUPRALOOP

Please provide your Indications for Use below.

?

The KARL STORZ SUPRALOOP is a monopolar electrosurgical device intended for cutting and removal of soft tissue in gynecological procedures involving endoscopic hysterectomy in adult women. It is used with standard electrosurgical generators

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92 and the FDA guidance document titled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" issued on July 28, 2014. All data included in this document is accurate and complete to the best of KARL STORZ SE & Co. KG knowledge.

Submitter:	KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34 78532 Tuttlingen, Germany
Contact:	Mario Trujillo Regulatory Affairs Specialist Tel.: (424) 218-8481 Email: Mario.Trujillo@karlstorz.com
Date of Preparation:	September 23, 2026
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ SUPRALOOP Classification Name: Coagulator-Cutter, Endoscopic, Unipolar (And Accessories) (21 CFR Part 884.4160);
Regulatory Class:	II
Product Code:	KNF
Guidance Document:	Not applicable
Predicate Devices:	LINA LOOP, MODELS: EL-160-4, EL-160-8, EL-200-4, EL-200-8 (K070315) The predicate has been subject to a design related recall. Due to the potential for the predicate device to break during a procedure, additional warnings were added to the instructions for use. KARL STORZ has adequately addressed the design related issues of the predicate through labeling and performance testing of the subject device.
Device Description:	The KARL STORZ SUPRALOOP is a modular monopolar electrosurgical system for laparoscopic supracervical hysterectomy. The system consists of a reusable handle (26183MA), a reusable 5 mm outer sheath with a 300 mm working length (26183MB), and a sterile, single-use monopolar loop electrode. Two loop sizes are available: 120 mm x 85 mm (26183MC-S) and 200 mm x 150 mm (26183MD-S). The patient-contacting materials of the loop include nickel-titanium alloy (NiTi), polytetrafluoroethylene (PTFE), stainless steel 1.4305, and black PTFE. The patient-contacting materials of the outer sheath include black polyphenylsulfone (PPSU), zirconium oxide (ZrO₂), black perfluoroalkoxy alkane (PFA), and gray silicone. The loop electrode is connected through the reusable handle and sheath to a commonly available electrosurgical generator with a monopolar output. When HF energy is activated, current is conducted through the loop electrode to circumferentially cut and coagulate tissue, with current returning through a separate patient return electrode. The handle advances and retracts the loop through the sheath to open and close the loop around the target tissue.
Indications For Use:	The KARL STORZ SUPRALOOP is a monopolar electrosurgical device intended for cutting and removal of soft tissue in gynecological procedures involving endoscopic hysterectomy in adult women. It is used with standard electrosurgical generators

Substantial equivalence	Comparison Table: Subject vs. Predicate Device		
		Subject Device KARL STORZ SUPRALOOP	Predicate Device, K070315 LiNA Loop
	Indication for Use		
	Indications for Use	The KARL STORZ SUPRALOOP is a monopolar electrosurgical device intended for cutting and removal of soft tissue in gynecological procedures involving endoscopic hysterectomy in adult women. It is used with standard electrosurgical generators.	The LiNA Gold Loop is a 5mm monopolar electrosurgical device intended for cutting and removal of soft issue in gynecological procedures involving endoscopic hysterectomy. It is used with standard electrosurgical generators.
	Product Code	KNF	KNF
	Target Population	Adult women	Adult women
	Physical & Technological Characteristics		
	Components	Handle, outer sheath, loop	Handle, outer sheath, loop
	Product Assembly and disassembly	Requires user assembly	Provided Assembled
	Sheath Working Length	300 mm	Information not available
	Sheath Total Length	413 mm	Information not available
	Outer Sheath Total Length	0.5 mm	0.5 mm
	Loop Working Length	120mm x 85mm 200mm x 150mm	160mm x 80mm 200mm x 100mm
	Loop Total Length	593 mm 680 mm	Information not available
	Method of Action	The loop opens when the handle is pushed forward. The loop closed when the handle is pushed backwards.	The loop opens when the handle is pushed forward. The loop closed when the handle is pushed backwards.
	Energy Source	Monopolar	Monopolar
	HF Generator Compatibility	Compatible with all standard electrosurgical generators with monopolar outlet.	Compatible with all standard electrosurgical generators with monopolar outlet.
	Cleaning and Sterilization Methods		
	Reusable Components	Handle, outer sheath	None
	Cleaning	Manual	N/A
	Sterilization	Steam, EtO	Steam, EtO
	Sterile Single-Use Components	Loop	All
Shelf Life	Loops: 5 years	Information not publicly available	
The subject and predicate devices have the same indications for use. Differences in design, dimensions, materials, assembly, and reprocessing were evaluated through bench, biocompatibility, sterility, packaging, shelf-life, electrical safety, and EMC testing. These differences do not raise different questions of safety or effectiveness.			

Non-Clinical Performance Data:	Bench verification performance testing has been performed for the following parameters: • Attaching and Detaching Force of the Electrode • System Interlocking Test • Bending Force • HF Tissue Test and HF Durability • Compression Testing • Tensile Strength Testing • Biocompatibility evaluation was performed to ISO 10993 The results met the predefined acceptance criteria and support the mechanical integrity and functional performance of the subject device Electrical safety and electromagnetic compatibility (EMC) Electrical safety and EMC testing were provided in the submission. The system complies with the IEC 60601-1, IEC 60601-2-2 standards for safety and the IEC 60601-1-2 standard for EMC. Biocompatibility The loop electrode and outer sheath were evaluated as external communicating devices with tissue contact for a limited duration of less than 24 hours in accordance with ISO 10993-1. The biological evaluation included: cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity and material-mediated pyrogenicity. All applicable acceptance criteria were met. Sterility The single-use loop electrodes are supplied sterile by ethylene oxide sterilization validated in accordance with ISO 11135:2014 to a sterility assurance level of 10^{-6}. EO and ECH residuals were evaluated in accordance with ISO 10993-7 and met the applicable allowable limits. A 5-year shelf life was supported by accelerated aging, climate conditioning, transportation simulation, seal-strength testing, package visual inspection, and package integrity testing. Packaging validation was performed in accordance with ISO 11607-1:2019, ASTM F88/F88M-15 and the bubble-leak method. The reusable handle and sheath are supplied non-sterile and require reprocessing prior to first use and in between uses. The submission includes validation of the cleaning and steam sterilization reprocessing instructions.
Clinical Performance Data:	Clinical testing was not required to demonstrate the substantial equivalence to the predicate device
Conclusion:	The results of the non-clinical performance testing support the substantial equivalence of the KARL STORZ SUPRALOOP to the legally marketed predicate device, LiNA Loop (K070315). The subject device has the same intended use and indications for use as the predicate. The identified technological differences do not raise different questions of safety or effectiveness, and the performance data demonstrate that the KARL STORZ SUPRALOOP is as safe and effective as the predicate device for its intended use.