September 8, 2023

Karl Storz SE & CO. KG
℅ Emily Rhiel
Regulatory Affairs Specialist
KARL STORZ Endoscopy-America, Inc.
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K230535
Trade/Device Name: KARL STORZ Urological Laser Accessories
Regulation Number: 21 CFR§ 878.4810
Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 4, 2023
Received: August 7, 2023

Dear Emily Rhiel:

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,

Mark J. Antonino -S

Mark J. Antonino, M.S.
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

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)*
K230535

Device Name
KARL STORZ Urological Laser Accessories

Indications for Use *(Describe)*
The KARL STORZ Urological Laser Accessories are used with laser fibers during urological endoscopic procedures.

The above indications are applicable to the following model numbers:
27026 VA
27026 VI
27026 VIL
27026 OV
27026 VS
27040 SL
27040 SD
27050 SL
27050 SC
27040 XA
27040 XAL
PV27040 XAL-1
27050 CA
27050 XA
27056 LA
27056 LB
27056 LE
27056 EA
27056 EB
27056 EC
27056 ED
27068 CD
27050 VL
27040 OC
27048 CK
27050 BE
27050 BK
27051 B
27500
27502
27026 VY

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:	Emily Rhiel Regulatory Affairs Specialist Phone: (774) 318-2820 Email: emily.rhiel@karlstorz.com
Date of Preparation:	February 27, 2023
Type of 510(k) Submission:	Traditional
Device Identification:	KARL STORZ Urological Laser Accessories
Regulatory Class:	II
Product Code:	GEX: Powered Laser Surgical Instrument
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR Part 878.4810)
Common Name:	Powered Laser Surgical Instrument
Device Panel:	Gastroenterology & Urology
Predicate Device(s):	K942786: KARL STORZ Laser Accessories
Device Description:	KARL STORZ Urological Laser Accessories are manually operated reusable surgical devices that are used with a cystoscope for examination, diagnosis, and/or therapy in the Urology discipline. Urological Laser Accessories may consist of: Sheaths, Obturators, Working Elements, Telescope Bridges, Working Inserts, Guiding Probes, and Adaptors. A laser fiber may be inserted through the sheath channel for surgical tissue ablation.

Indications for Use:	The KARL STORZ Urological Laser Accessories are used with laser fibers during urological endoscopic procedures.

Model Numbers:

Accessory Type	Model Number	Description
Cystoscope Accessories		
Sheaths	27026 VA	Outer Sheath, 23 Fr.
	27026 VI	Inner Sheath, with 7.5Fr. working channel
	27026 VIL	Inner Sheath
Obturators	27026 OV	Obturator, 23 Fr.
	27026 VS	Visual Obturator
Resectoscope Accessories		
Sheaths	27040 SL	Resectoscope Sheath, 26 Fr.
	27040 SD	Resectoscope Sheath, 26 Fr.
	27050 SL	Resectoscope Sheath, 26 Fr.
	27050 SC	Resectoscope Sheath, 26 Fr.
	27040 XA	Inner Sheath for 27040 SD/SL
	27040 XAL	Inner Tube for 27040 SD/SL
	PV27040 XAL-1	Inner Tube
	27050 CA	Inner Sheath for 27050 SC
	27050 XA	Inner Sheath for 27050 SL
Working Elements	27056 LA	Working Element
	27056 LB	KUNTZ Working Element
	27056 LE	LASER Working Element
Guiding Probes	27056 EA	LASER Guide Probe, 0.8 mm
	27056 EB	LASER Guide Probe, 1.5 mm
	27056 EC	LASER Guide Probe, 0.8 mm
	27056 ED	LASER Guide Probe, 1.5 mm
Telescope Bridge	27068 CD	Telescope Bridge
Working Insert	27050 VL	LASER Working Insert
Obturators	27040 OC	Standard Obturator
	27048 CK	Deflecting Obturator, 24/26 Fr.
	27050 BE	Visual Obturator, for sheaths 24/26 Fr.
	27050 BK	Visual Obturator, for sheaths 24/26 Fr.
	27051 B	SCHMIEDT Visual Obturator, 24/26 Fr.
Compatible Components		
LUER-Lock Tube Connectors	27500	LUER-Lock Tube Connector
	27502	LUER-Lock Tube Connector
Adaptor	27026 VY	LASER Cystoscope Adaptor

Technological Characteristics:

	Subject Device KARL STORZ Urological Laser Accessories	**Predicate Device** KARL STORZ Laser Accessories K942786
System Components	Sheath; obturator; working element; guide probe; working insert; bridge; laser adaptor; LUER-Lock tube connector	Sheath; obturator; cannulae; endoscopes; adaptor; bridge; deflection device; backstop; protector
Irrigation and Aspiration	Continuous flow	Same as subject
Sheath	Diameter: 23.5 – 27.6Fr. Length: 216.5 – 239mm	Diameter range: 21 – 24Fr Length: 235 – 260.5mm
Obturator	Diameter: 19.9 – 21Fr. Length: 249.5 – 311.7mm	Diameter: 17.9 – 21.15Fr. Length: 246.5 – 377.8mm
Laser Guide Probe	Length: 342.7mm-345.7mm	N/A
Working Element	Diameter: 1 x 4.4mm, 1x 2.5mm Length: 2x 4.4mm	N/A
Telescope Bridge	Number of channels: 1	Number of channels: 1 – 2

Non-Clinical Performance Data:

The following non-clinical performance data were provided in support of the substantial equivalence determination.

<u>Biocompatibility testing</u>

The system complies with the following standards:

- ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-2: Biological evaluation of medical devices – Part 2: Animal welfare requirements
- ISO 10993-5: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests skin sensitization
- ISO 10993-11: Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- ISO 10993-12: Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

	○ ISO 10993-18: Biological evaluation of medical devices – Part 18: Chemical characterization of materials ○ ISO 10993-23 Biological evaluation of medical devices – Part 23: Tests for irritation 2021 <u>Reprocessing Validation Summary</u> The reprocessing data submitted complies with the following standards: ○ ISO 14937: Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices ○ ISO 17665-1: Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices ○ AAMI TIR 30:2011: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. ○ ASTM F3208-17, 2017: Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices ○ ISO 15883-5: Washer Disinfectors – Test soils and methods for demonstrating cleaning efficacy <u>Bench Performance Testing</u> Additional bench testing was performed to ensure the device met its design specifications and is substantially equivalent to its predicate device. ○ System Interlocking Test ○ Flow Test (comparative) ○ Bending Force Test
Clinical Performance Data:	Clinical testing was not required to demonstrate the substantial equivalence to the predicate device. Non-clinical bench testing was sufficient to assess safety and effectiveness and to establish the substantial equivalence of the modifications.
Conclusion:	The conclusions drawn from the non-clinical performance data demonstrated that the subject device is as safe as and as effective as the predicate device. As such, we concluded that the substantial equivalence of the subject and the predicate device has been met, and the differences between the subject and the predicate device do not raise new questions of safety and effectiveness.