June 6, 2025

Karl Storz Se & Co. Kg
Emily Rhiel
Regulatory Affairs Specialist
Dr. Karl-Storz-Straße 34
Tuttlingen, BW 78532
GERMANY

Re: K243550
Trade/Device Name: KARL STORZ Flexible Video-Uretero-Renoscope (FLEX XC)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FGB
Dated: May 7, 2025
Received: May 7, 2025

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 (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.

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,

Mark J. Antonino -S

Mark 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243550

Device Name

KARL STORZ Flexible Video-Uretero-Renoscope (FLEX XC)

Indications for Use *(Describe)*

Flexible Video-Uretero-Renoscope (Flex XC)
The KARL STORZ Flexible Video-Uretero-Renoscope is indicated for endoscopic examination in the urinary tract and can be used to examine the interior of the kidney, and using additional accessories,

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

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 Senior Regulatory Affairs Specialist Phone: (774) 318-2820 Email: emily.rhiel@karlstorz.com
Date of Preparation:	June 6, 2025
Type of 510(k) Submission:	Traditional
Device Identification:	Flexible Video-Uretero-Renoscope (FLEX-XC)
Regulatory Class:	II
Product Code:	FGB
Classification Name:	Ureteroscope and accessories, Flexible/Rigid (21 CFR Part 876.1500)
Device Panel:	Gastroenterology & Urology
Predicate Device(s):	K141250 KARL STORZ Flexible Video-Uretero-Renoscope
Device Description:	The KARL STORZ Flexible Video-Uretero-Renoscope (PNs 11278VSE, 11278VSUE) is a video endoscope used for visualization within the upper urinary tract (ureters) and kidneys. The endoscope includes a luer with two ports to allow access for instrumentation, as well as irrigation. The Flexible Video-Uretero-Renoscope models 11278VSE and 11278VSUE differ only in the direction of the distal tip deflection. With 11278VSUE when the control lever is pushed forward towards the distal tip, the distal tip deflects down and with 11278VSE the deflection is opposite.
Indications for Use:	Flexible Video-Uretero-Renoscope (Flex XC) The KARL STORZ Flexible Video-Uretero-Renoscope is indicated for endoscopic examination in the urinary tract and can be used to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures.

Physical and Technological Characteristics:

	Subject Device Flexible Video-Uretero-Renoscope	**Predicate Device Videoscope: K141250** Flexible Video-Uretero-Renoscope
Endoscope Type	Flexible CMOS video endoscope	Same as subject

	Camera Control Unit	Image 1 S CCU (Connect and Link modules required)	Same as subject
	Deflection	285° up/down 270° with instruments in the working channel	270° up/down
	Working Length	675mm	Same as subject
	Working Channel Diameter	1.2mm	Same as subject
	Outer Diameter	2.9mm	Same as subject
	Light Source	Internal LED	Same as subject
	Direction of View	0°	Same as subject
	Field of View	80-110°	80-95°

Non-Clinical Performance Data:

Biocompatibility Evaluation

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

Reprocessing Validation

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
- ANSI / AAMI ST98: Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices
- ASTM F3208-20: Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices.
- ISO 17664-1: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of

	medical devices - Part 1: Critical and semi-critical medical devices • ANSI / AAMI ST77: Containment Devices for Reusable Medical Device Sterilization. • ISO 22441:2022. Sterilization of Health Care Products – General Requirements for Characterization of a Sterilization Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices. <u>Bench Performance Testing</u> The bench performance data submitted complies with the following standards: • ISO 8600-1: Endoscopes - Medical endoscopes and endotherapy devices -- Part 1: General requirements • ISO 8600-3: Endoscopes - Medical endoscopes and endotherapy devices Part 3: Determination of field of view and direction of view of endoscopes with optics • IEC 62471: Photobiological safety of lamps and lamp systems
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 demonstrates that the subject device is as safe as and as effective as the predicate device. As such, we conclude 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.