June 3, 2026

Karl Storz Se & Co. Kg
Jennifer Downing
Senior Regulatory Affairs Specialist
Dr.-Karl-Storz-Straße 34
Tuttlingen, BW 78532
GERMANY

Re: K252800
Trade/Device Name: KARL STORZ Endoscopic Accessories for Urology
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCZ
Dated: May 2, 2026
Received: May 4, 2026

Dear Jennifer Downing:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 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,

Mark R. Kreitz -S

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

510(k) Number *(if known)*
K252800

Device Name
KARL STORZ Endoscopic Accessories for Urology

Indications for Use *(Describe)*
The indications for use are the same for all subject devices, except for differences in which devices are indicated for use in pediatric populations.

• For 11274FE, 11274ZE, 27023FM, 27095F, 27095P, 27095Z:
Endoscopic accessories for urology are indicated for use by qualified surgeons during endoscopic surgical urology procedures, such as cystoscopy, urethroscopy, ureteroscopy and ureterorenoscopy for patients from birth and older.

• For 27034FK, 27034FL, 27034S:
Endoscopic accessories for urology are indicated for use by qualified surgeons during endoscopic surgical urology procedures, such as cystoscopy, urethroscopy, ureteroscopy and ureterorenoscopy for patients 2 years of age and older.

• For 11275FE, 11275ZE, 27023FE, 27023ZE, 27035D, 27035F, 27035L, 27035S, 27178A, 27178B, 27424F, 27424P, 27424R, 27424U, 27424Z, 27425F, 27425FG, 27425P, 27425PG, 27425R, 27425RG, 27425U, 27425Z, 27425ZG:
Endoscopic accessories for urology are indicated for use by qualified surgeons during endoscopic surgical urology procedures, such as cystoscopy, urethroscopy, ureteroscopy and ureterorenoscopy in adults.

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. All data included in this document is accurate and complete to the best of KARL STORZ's knowledge.

Submitter:	KARL STORZ SE & CO. KG (KST) Dr.-Karl-Storz-Straße 34 Tuttlingen, Baden-Wurttemberg, Germany, 78532 Establishment Registration Number: 9610617
Contact:	Jennifer Downing Senior Regulatory Affairs Specialist jennifer.downing@karlstorz.com Tel.: 1-424-218-8115
Date of Preparation:	May 25, 2026
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ Endoscopic Accessories for Urology
Common Name:	Endoscopic Accessories for Urology
Regulatory Class:	II
Product Code:	OCZ
Classification Name:	Endoscopic Grasping/Cutting Instrument, Non-Powered
Device Panel:	Gastroenterology/Urology
Predicate Device(s):	K950434, KARL STORZ Flexible Accessories for Endoscopic Urology Procedures The predicate devices have not been subject to any recalls.
Device Description:	The devices are manual surgical, stainless steel instruments for grasping, biopsy taking and cutting. At the proximal end there is a handle. Operating the handles is mechanically transmitted to the jaw part causing the branches to move (open/close). The instrument shaft is inserted through the working channel of an endoscope or sheath into the operating field, and the cutting/grasping/biopsy taking is controlled by opening and closing the

	handles. The instrument shafts can be rigid, semi-rigid (bendable) or fully flexible. Instruments are available from 3-9 Fr in diameter and 30-100 cm in working length. The distal tip/jaw has the following variations: • Biopsy Forceps, for tissue biopsy • Scissors, for the cutting of tissue • Splitting forceps and through-cutting forceps, for breaking apart kidney, bladder, or ureter stones • Grasping Forceps, for grasping and removing stone fragments, tissue and foreign bodies such as stents
Indications For Use:	The indications for use are the same for all subject devices, except for differences in which devices are indicated for use in pediatric populations. • For 11274FE, 11274ZE, 27023FM, 27095F, 27095P, 27095Z: Endoscopic accessories for urology are indicated for use by qualified surgeons during endoscopic surgical urology procedures, such as cystoscopy, urethroscopy, ureteroscopy and ureterorenoscopy for patients from birth and older. • For 27034FK, 27034FL, 27034S: Endoscopic accessories for urology are indicated for use by qualified surgeons during endoscopic surgical urology procedures, such as cystoscopy, urethroscopy, ureteroscopy and ureterorenoscopy for patients 2 years of age and older. • For 11275FE, 11275ZE, 27023FE, 27023ZE, 27035D, 27035F, 27035L, 27035S, 27178A, 27178B, 27424F, 27424P, 27424R, 27424U, 27424Z, 27425F, 27425FG, 27425P, 27425PG, 27425R, 27425RG, 27425U, 27425Z, 27425ZG: Endoscopic accessories for urology are indicated for use by qualified surgeons during endoscopic surgical urology procedures, such as cystoscopy, urethroscopy, ureteroscopy and ureterorenoscopy in adults.

Comparison with Predicate Device Indications for Use:

The **Predicate Device (K950434)** Indications for Use / Intended Use are:

- KARL STORZ Flexible Accessories for Endoscopic Urology Procedures are intended for use by qualified surgeons for endoscopic surgical procedures in Urology.

Comparing phrasing between the Predicate and Subject Devices, with differences underlined:

Predicate K950434	**Subject Device**
Flexible Accessories for Endoscopic Urology	Endoscopic accessories for urology
are intended for use by qualified surgeons	are indicated for use by qualified surgeons
for endoscopic surgical procedures in Urology.	during endoscopic surgical urology procedures
	such as [examples of procedures]
	[patient age ranges]

Summarizing the table above, the differences in Indications for Use are limited to:

- Removal of a descriptive word ("flexible"). Does not change the use of the device.
- Word order changes (e.g., "Accessories for Endoscopic Urology" vs "Endoscopic accessories for urology"). The meaning remains the same; does not change the use of the device.
- At the end, after "during endoscopic surgical procedures", the subject device Indications for Use adds "such as …" and names examples of these types of procedures. Since these are already included in the larger, more general group (endoscopic surgical urology procedures), and this group is the same for both the subject and predicate devices, there is no change to the use of the device.
- The subject device names patient age ranges, including pediatric populations. The predicate device did not specify a

patient population. For the subject device, the use of the device for the specified age ranges was supported by formal review of the clinical literature. This review determined that the safe and effective use of KARL STORZ Urological Instruments in these pediatric populations (infants, children, and adolescents) is adequately substantiated by the reviewed clinical literature.

Summary: The differences between the subject device indications, and the predicate device indications, are not critical to the intended use of the device, and the differences do not affect the safety or effectiveness of the device when used as labeled.

Technological Characteristics:

The comparison of technological characteristics is as follows:

Comparison	Subject Device	Predicate K950434
Type of Device	Grasping Forceps Biopsy Forceps Cutting Forceps/Scissors	Same as subject device
Jaw width (Diameter)	3 to 9 Fr. (1.0 to 3.0 mm)	Same as subject device
Working length	30 - 100 cm	28 - 100 cm
Shaft Type	Flexible, semi-rigid, rigid	Flexible
Jaws Opening	Double- or Single-Action Jaws	Same as subject device
Jaws characteristics	Grasping (grasping forceps) Cutting and Grasping (biopsy forceps) Cutting (cutting forceps / scissors)	Same as subject device

	As shown in the table above, the majority of the technological characteristics are the same for both the subject and predicate device, including the size range (the range is smaller for the subject device than predicate device).
	One characteristic, the shaft type, is technologically different than the predicate device. The predicate device was only available with a flexible shaft. The subject device has additional shaft types, semi-rigid and rigid. These differ both in design and in the required reprocessing methodology. In order to verify that these differences do not raise new questions of safety and effectiveness, testing was carried out. In order to demonstrate equivalence with the predicate device for all subject devices, the testing was performed out on all of the subject device types (flexible, semi-rigid, and rigid).
	• Reprocessing validation: confirmed that the subject device can be consistently sterilized.
	• Bench Testing:
	  ○ Load force: confirmed the devices are not damaged by the forces used in their indicated procedures
	  ○ System Interlocking: confirmed the devices are correctly sized and configured to fit with their compatible access systems.
	  ○ Cutting Performance: confirmed that the scissors/cutting forceps make clean cuts.
	  ○ Grasping Performance: confirmed that the grasping forceps can successfully grasp and remove objects.
	Based on the results of the bench testing and reprocessing validation, the subject device is substantially equivalent to the predicate device.
	
	In summary, the subject device is substantially equivalent to the predicate device, and the technological differences between them do not raise any different questions of safety and effectiveness.

Non-Clinical Performance Data:	There are no performance standards or special controls developed under Section 514 of the FD&C Act for Endoscopic Accessories for Urology. However, the subject device follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance:

	<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 <u>Reprocessing Validation</u> The reprocessing data submitted complies with the following standards and guidance with regards to cleaning and sterilization: • 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 • TIR12:2020: Designing testing and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers • ST79:2017: Comprehensive guide to steam sterilization and sterility assurance in health care facilities • 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 • FDA Guidance Document Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling • ANSI / AAMI ST98: Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices • ANSI/AAMI ST77: Containment devices for reusable medical device sterilization <u>Bench Testing:</u> The following mechanical performance testing was performed and submitted. There were no applicable standards or guidance specific for this testing. For descriptions of this testing, see Technological Characteristics. • System Interlocking • Cutting Performance • Grasping Performance • Load force
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 nonclinical tests demonstrate that the subject device, KARL STORZ Endoscopic Accessories for Urology, is substantially equivalent to the predicate device that is currently marketed for the same intended use.