July 25, 2024

Karl Storz SE & Co. Kg
℅ Jordan Lydia Verla
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K233372
Trade/Device Name: KARL STORZ Fiber Telescopes for Urology
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB
Dated: June 14, 2024
Received: June 14, 2024

Dear Jordan Lydia Verla:

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,

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)*
K233372

Device Name
KARL STORZ Fiber Telescopes for Urology

Indications for Use *(Describe)*
For devices (27033C, 27033CR, 27033D, 27033F, 27033CRO, 27033CO, 27033DO, 27001E, 27001G, 27001GH, 27001GF, 27014Y)
The sheaths, obturators, and accessories when used with compatible endoscopes are intended to provide visualization and access to operative site during minimal invasive urological endoscopic procedures in adults and pediatrics.

For telescopes (27000K, 27000L, 27010K, 27010L, 27002KP, 27030KA, 27030KB)
The endoscopes are intended to provide visualization of the operative site during minimal invasive urological endoscopic procedures in adults and pediatrics.

For telescopes (27001K, 27001L, 27002K, 27002L, 27003L, 27011K, 27011L)
The endoscopes are intended to provide visualization of the operative site during minimal invasive urological endoscopic procedures 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 KSEA's knowledge.

Submitter:	KARL STORZ SE & CO. KG Dr.-Karl-Storz-Straße 34 TUTTLINGEN, Baden-Wurttemberg GERMANY, 78532
Contact:	Jordan Lydia Verla Senior Regulatory Affairs Specialist Tel: (424) 218-8100 ext. 8382 Email: Jordan.Verla@karlstorz.com
Date of Preparation:	September 30, 2023
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ Fiber Telescopes for Urology Common Name: Ureteroscope and accessories, flexible/rigid Classification Name: Endoscope and accessories (21 CFR 876.1500)
Regulatory Class:	II
Product Code:	FGB
Classification Panel:	Gastroenterology/Urology
Predicate Device(s):	KARL STORZ Uretero Renoscopes/Ureteroscopes (K940464)
Device Description:	KARL STORZ Fiber Telescopes for Urology are manually operated reusable surgical devices that fall into the following categories: Urethroscopes / Ureteroscope / Uretero-Renoscope, modular scope, sheaths, telescopic bridges, luer lock tube connectors, obturators, insertion aids, adapters. The KARL STORZ Fiber Telescopes for urology are semi-rigid telescopes that utilize fiber optic technology. The shaft of the endoscopes consists of phynox or stainless steel. An optical fiber bundle runs through a central lumen in the shaft and transmits the image received at the distal end to the eyepiece. Other fibers illuminate the operative site by transmitting light. An operating, or working channel, provides instruments access to the operative site. The

KARL STORZ Fiber Telescopes are available in the following:

Direction of View	0°, 7°
Field of View	95,5°, 96.5°
Diameter	Graduated 7Fr, 8Fr, 10Fr, 12Fr
Working Length	13cm, 25cm, 34cm, 43cm
Working Channel	3.5Fr, 4.5Fr, 5Fr, 6Fr

Indications for Use:

Indications for Use are in the Technological Characteristics section, below.

Technological Characteristics:

The subject and predicate device have similar technological characteristics and similar operating principles as the subject device.

	KARL STORZ Fiber Telescopes for Urology Subject Device	**KARL STORZ Uretero-Renoscopes / Ureteroscopes Predicate Device K940464**
Indications for Use	For devices (27033C, 27033CR, 27033D, 27033F, 27033CRO, 27033CO, 27033DO, 27001E, 27001G, 27001GH, 27001GF, 27014Y) The sheaths, obturators, and accessories when used with compatible endoscopes are intended to provide visualization and access to operative site during minimal invasive urological endoscopic procedures in adults and pediatrics. For telescopes (27000K, 27000L, 27010K, 27010L, 27002KP, 27030KA, 27030KB) The endoscopes are intended to provide visualization of the operative site during minimal invasive urological endoscopic procedures in adults and pediatrics. For telescopes (27001K, 27001L, 27002K, 27002L, 27003L, 27011K, 27011L)	The Storz Uretero-Renoscopes Ureteroscopes are designed to permit a physician or surgeon to view the operative site during minimally invasive urological endoscopic or laparoscopic procedures.

	The endoscopes are intended to provide visualization of the operative site during minimal invasive urological endoscopic procedures in adults.	
Product Code(s)	FGB	FGB
Target Population	Adults & Pediatrics	Adults & Pediatrics
Anatomical Site	Upper Urinary Tract	Upper Urinary Tract
Where Used	Hospital	Hospital
Endoscope Type	Semi-Rigid	Semi-Rigid
Optical Design / Technology	Fiber Optic	Fiber Optic
Direction of View	0°, 7°	0°
Diameter	Graduated 7Fr, 8Fr, 10Fr, 12Fr	Graduated 7Fr, 9.5Fr, 10.5Fr, 11Fr, 13Fr
Working Length	13cm, 25cm, 34cm, 43cm	11cm, 34cm, 43cm, 44.5cm
Working Channel	3.5Fr, 4.5Fr, 5Fr, 6Fr	3.5Fr, 5Fr
Field of View	95,5°, 96.5°	0°, 74°, 96.5°
Light Source	External	External
Patient Contacting Material	Scopes: Cobalt-Chromium-Nickel Alloy, Stainless Steel, Silver Solder, Epoxy Adhesive, Sapphire Glass, Glass Fibers, Sheaths: Surgical Stainless Steel, Silver Brazing Alloy, Epoxy Adhesive, Lubricant, Ester + PTFE Bridges: Surgical Stainless Steel Luer Lock Connectors: Stainless Steel, Lubricant, Ester + PTFE, Coating	Chromium Plated Monel 400
Cleaning	Manual	Manual
Sterilization	**Scopes:** (27003L, 27030KA, 27030KB, 27002KP, 27000L, 27001L, 27011L, 27002L, 27000K, 27001K, 27011K, 27002K): Steam Sterilization	EO, HLD (2% glutaraldehyde)

		(27010L, 27010K): Steam Sterilization; STERRAD 100NX; V-PRO 1 Cycle, V-PRO 1 Plus Lumen Cycle, V-PRO Max Lumen Cycle, V-PRO Max 2 Lumen Cycle **Sheaths:** Steam Sterilization **Bridges:** Steam Sterilization **Luer-Lock Connectors:** Steam Sterilization **Obturators:** Steam Sterilization **Insertion Aids:** Steam Sterilization **Adapters/Instrument Ports:** Steam Sterilization	
Non-Clinical Performance Data:	There are no performance standards or special controls developed under Section 514 of the FD&C Act for endoscopes. However, the HOPKINS Telescopes follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance: **ISO Endoscopic Standards** • ISO 8600-1 • ISO 8600-3 • ISO 8600-5 • ISO 8600-6 **Biocompatibility Summary** • Cytotoxicity (ISO 10993-5) • Acute Systemic Toxicity (ISO 10993-11) • Intracutaneous Irritation (ISO 10993-10) • Maximization Sensitization (ISO 10993-10) **Electrical Safety and EMC** • IEC 60601-2-18 (3RD Edition) **Reprocessing (Cleaning and Sterilization)** • AAMI TIR12: 2010		

	• AAMI TIR30: 2011 • ANSI/AAMI ST8: 2013 • ANSI/AAMI ST77:2013 • ANSI/AAMI ST79:2017 • ANSI/AAMI ST81:2004/(R)2010 • AAMI/ISO 14937:2009 • ANSI/AAMI/ISO 17655-1:2006/2013 • Reprocessing Medical Device in Health Care Settings: Validation Methods and Labeling Comparative bench testing between the subject and predicate device demonstrated that the KARL STORZ Fiber Telescopes for Urology has met all its design specification and is substantially equivalent to its predicate device.
Clinical Performance Data:	Published literature was provided to support the safety and effectiveness of the KARL STORZ Fiber Telescopes for Urology for use in pediatrics during minimal invasive urological endoscopic procedures.
Conclusion:	The conclusions drawn from the nonclinical test demonstrate that the subject device is as safe and effective as the predicate device.