November 18, 2025

Karl Storz Se & Co. Kg
Jordan Lydia Verla
Senior Regulatory Affairs Specialist
Dr.-Karl-Storz-Straße 34
Baden-Wurttemberg
Tuttlingen, 78532
GERMANY

Re: K253411
Trade/Device Name: Miniature Telescope for Urology (27033AA)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: September 30, 2025
Received: September 30, 2025

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: 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 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 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

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.	Not Yet Assigned

Please provide the device trade name(s).

Miniature Telescope for Urology (27033AA)

Please provide your Indications for Use below.

For telescope (27033AA)
The endoscopes when used with sheaths and obturators are intended to provide visualization of the operative site during minimal invasive urological endoscopic procedures in adults and pediatrics.

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

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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, 2025
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: Miniature Telescope for Urology (27033AA) Common Name: Ureteroscope and Accessories Classification Name: Ureteroscope and Accessories, Flexible/Rigid
Regulatory Class:	II
Product Code:	FGB
Classification Panel:	Gastroenterology/Urology
Predicate Device(s):	KARL STORZ Fiber Telescopes for Urology (K233372) KARL STORZ Uretero Renoscopes/Ureteroscopes (K940464)
Device Description:	The *Miniature Telescope for Urology (27033AA)* is a semi-rigid telescope that utilizes fiber optic technology. The shaft of the endoscope 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. The *Miniature Telescope for Urology (27033AA)* is just an optic, without a working or irrigation channel. It is always used in combination (e.g. with sheath (or working element and sheath). Thus providing instruments access to the operative site. The *Miniature Telescope for Urology (27033AA)* is available in the following:

	<table><tr><td>Direction of View</td><td>0°</td></tr><tr><td>Field of View</td><td>72.5°</td></tr><tr><td>Diameter</td><td>3.5Fr</td></tr><tr><td>Working Length</td><td>21cm</td></tr></table>
Indications for Use:	*Indications for Use:* For telescope (27033AA) The endoscopes when used with sheaths and obturators are intended to provide visualization of the operative site during minimal invasive urological endoscopic procedures in adults and pediatrics.
Technological Characteristics:	The subject and predicate devices have similar technological characteristics and similar operating principles as the subject device. <table><tr><th></th><th>KARL STORZ Miniature Telescope for Urology Subject Device</th><th>KARL STORZ Fiber Telescopes for Urology Primary Predicate Device (K233372)</th><th>KARL STORZ Uretero-Renoscopes / Ureteroscopes Secondary Predicate Device (K940464)</th></tr><tr><td>Endoscope Type</td><td>Semi-Rigid</td><td>Semi-Rigid</td><td>Semi-Rigid</td></tr><tr><td>Optical Design / Technology</td><td>Fiber Optic</td><td>Fiber Optic</td><td>Fiber Optic</td></tr><tr><td>Direction of View</td><td>0°</td><td>0°, 7°</td><td>0°</td></tr><tr><td>Diameter</td><td>3.5Fr</td><td>Graduated 7Fr, 8Fr, 10Fr, 12Fr</td><td>Graduated 7Fr, 9.5Fr, 10.5Fr, 11Fr, 13Fr</td></tr><tr><td>Working Length</td><td>21cm</td><td>13cm, 25cm, 34cm, 43cm</td><td>11cm, 34cm, 43cm, 44.5cm</td></tr><tr><td>Field of View</td><td>72.5°</td><td>95,5°, 96.5°</td><td>0°, 74°, 96.5°</td></tr><tr><td>Light Source</td><td>External</td><td>External</td><td>External</td></tr></table>
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 subject device 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) • Material-Mediated Pyrogenicity (ISO 10993-11) **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 *Miniature Telescope for Urology (27033AA)* has met all its design specification and is substantially equivalent to its predicate device.
Clinical Performance Data	Clinical testing was not required to demonstrate substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to assess safety and effectiveness and to support substantial equivalence.
Conclusion:	The conclusions drawn from the non-clinical tests demonstrate that the subject device, the *Miniature Telescope for Urology (27033AA)* and accessories is as safe and effective as the predicate devices and supports substantial equivalence to the predicate devices.