



May 2, 2025

Karl Storz SE & CO. Kg
Thomas Ostrowski
Senior Regulatory Affairs Specialist
Dr.-Karl-Storz-Straße 34
Tuttlingen, BW 78532
GERMANY

Re: K244001
Trade/Device Name: KARL STORZ Cysto-Urethro-Fiberscope (11272CU1);
KARL STORZ Cysto-Urethro-Fiberscope (11272C2)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBO
Received: April 2, 2025

Dear Thomas Ostrowski:

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 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

Submission Number (if known)

K244001

Device Name

KARL STORZ Cysto-Urethro-Fiberscope (11272CU1);
KARL STORZ Cysto-Urethro-Fiberscope (11272C2)

Indications for Use (Describe)

The KARL STORZ Cysto-Urethro-Fiberscope and accessories are indicated for visualization and operative access during diagnostic and therapeutic endoscopic procedures of the urinary tract including the urethra and bladder.

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.

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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' knowledge.

Submitter:	KARL STORZ SE & CO. KG Dr.-Karl-Storz-Straße 34 Tuttlingen, BW 78532 Germany
Contact:	Thomas Ostrowski Regulatory Affairs Manager thomas.ostrowski@karlstorz.com Tel: +1 (508) 248-2420
Date of Preparation:	April 25, 2025
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ Cysto-Urethro-Fiberscope Models: 11272CU1 / 11272C2
Regulatory Class:	II
Product Code:	FBO (Cystourethroscope)
Regulation:	21 CFR 876.1500 – Endoscope and accessories
Device Panel:	Gastroenterology & Urology
Predicate Device:	KARL STORZ CYSTOSCOPE ENDOSCOPE,FIBEROPTIC (11277A/AU) – K945185 The K945185 device was subject to a reprocessing-related recall, which was resolved via a labeling update to discontinue use of high-level disinfection (HLD) reprocessing for the affected scopes. HLD reprocessing is not used for the subject device in this 510(k) submission. The predicate device has not been subject to any design-related recalls applicable to the current submission.
Reference Device:	OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5; CYF-5R – K221690
Device Description:	The KARL STORZ Cysto-Urethro-Fiberscope and Accessories consists of a flexible fiber endoscope (Model Number: 11272CU1 / 11272C2) which can be used standalone or connected to compatible FDA-cleared camera heads which transfer images to compatible FDA-cleared Computer Control Units (CCUs) for the purposes of

	visualization and operative access during diagnostic and therapeutic endoscopic procedures of the urinary tract including the urethra and bladder.		
Environment of Use:	The KARL STORZ Cysto-Urethro-Fiberscope and accessories is intended to be used only in healthcare facilities/hospitals.		
Indications for Use:	The KARL STORZ Cysto-Urethro-Fiberscope and accessories are indicated for visualization and operative access during diagnostic and therapeutic endoscopic procedures of the urinary tract including the urethra and bladder.		
Technological Characteristics:	The comparison of technological characteristics is as follows:		
		Subject Device	Predicate K945185
	Type of Scope	Flexible	Same as the subject device
	Diameter of working channel	2.33 mm	Same as the subject device
	Working shaft length	370 mm	Same as the subject device
	Working shaft diameter	5.25 mm	5.07 mm
	Light source	External	Same as the subject device
	Direction of view	0°	Same as the subject device
	Field of view	116°	Similar to the subject device
	Viewer	Eyepiece	Same as the subject device
	Distal Tip Deflection	210° Up 140° Down	180° Up 140° Down
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 guidances: <u>Biocompatibility Testing</u> The system complies with the following standards and guidance: FDA 2023 biocompatibility guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical		

devices - Part 1: Evaluation and testing within a risk management process”.

- ISO 10993-2:2006/(R)2014: Biological evaluation of medical devices – Part 2: Animal welfare requirements
- ISO 10993-5:2009/(R)2014: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021: Biological evaluation of medical devices – Part 10: Tests skin sensitization
- ISO 10993-11:2017: Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- ISO 10993-12:2021: Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
- ISO 10993-18:2020: Biological evaluation of medical devices – Part 18: Chemical characterization of materials
- ISO 10993-23:2021: Biological evaluation of medical devices – Part 23: Tests for irritation 2021

Reprocessing Validation Summary

The submitted reprocessing data complies with the following standards and guidance with regards to cleaning and sterilization:

- ANSI / AAMI / ISO 14937:2009/(R)2013 - 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
- ANSI / AAMI ST98:2022 - 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 17664-1:2021 - 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
- 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
- AAMI TIR12:2020/(R)2023 - Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
- FDA Guidance Document: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

	<u>Bench Performance Testing</u> Additional bench testing was performed to ensure that the device met its design specifications and is substantially equivalent to the predicate devices. This testing complies with the following standards: • IEC 60601-2-18:2009 • IEC 62471:2006 • ISO 8600-3:2019 • ISO 8600-5:2020 A summary of bench performance test results included in the submission is listed below: • Bench testing – Mechanical Performance Verification • Bench testing – Optical Performance Verification • Bench testing – Photobiological Safety A summary of bench performance test results referenced in the submission is listed below: • Bench testing – Thermal Safety
Clinical Performance Data	Clinical testing was not required to demonstrate substantial equivalence to the predicate device. 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 KARL STORZ Cysto-Urethro-Fiberscope and accessories is as safe and effective as the predicate device and supports substantial equivalence to the predicate device.