November 27, 2024

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

Re: K243409
Trade/Device Name: KARL STORZ Pediatric Cysto-Urethro-Fiberscope (11274BCU1)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBO
Dated: October 31, 2024
Received: November 1, 2024

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 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.

Submission Number *(if known)*

K243409

Device Name

KARL STORZ Pediatric Cysto-Urethro-Fiberscope (11274BCU1)

Indications for Use *(Describe)*

The KARL STORZ Pediatric Cysto-Urethro-Fiberscope and accessories are intended for use by a physician in the visual examination and treatment of a variety of urological endoscopic procedures for pediatric patients.

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' knowledge.

Submitter:	KARL STORZ SE & CO. KG Dr.-Karl-Storz-Straße 34 Tuttlingen, BW 78532 Germany
Contact:	Thomas Ostrowski Senior Regulatory Affairs Specialist thomas.ostrowski@karlstorz.com Tel: +1 (508) 248-2420
Date of Preparation:	November 26, 2024
Type of 510(k) Submission:	Special
Device Identification:	Trade Name: KARL STORZ Pediatric Cysto-Urethro-Fiberscope Models: 11274BCU1
Common Name:	Cystourethroscope
Classification Name:	Cystourethroscope
Regulatory Class:	II
Product Code:	FBO
Regulation:	876.1500 – Endoscope and accessories
Device Panel:	Gastroenterology & Urology
Predicate Device(s):	Primary Predicate Device: K241945 KARL STORZ Pediatric Cysto-Urethro-Fiberscope and Accessories (11278ACU1 / 11278AC2) The predicate device has not been subject to a design-related recall.
Device Description:	The KARL STORZ Pediatric Cysto-Urethro-Fiberscope and Accessories consists of a flexible fiber endoscope (Model Number: 11274BCU1) 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 visual examination and treatment of a variety of urological endoscopic procedures for pediatric patients.

<table>
<tr><td>Environment of Use:</td><td>The KARL STORZ Pediatric Cysto-Urethro-Fiberscope and Accessories is intended to be used only in healthcare facilities/hospitals.</td></tr>
<tr><td>Indications for Use:</td><td>The KARL STORZ Pediatric Cysto-Urethro-Fiberscope and Accessories are intended for use by a physician in the visual examination and treatment of a variety of urological endoscopic procedures for pediatric patients.</td></tr>
<tr><td>Technological Characteristics:</td><td>The comparison of technological characteristics is as follows:
<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device K241945</th></tr>
<tr><td>Type of Scope</td><td>Flexible</td><td>Same as the subject device</td></tr>
<tr><td>Diameter of working channel</td><td>1.2 mm</td><td>Same as the subject device</td></tr>
<tr><td>Working shaft length</td><td>250 mm</td><td>450 mm</td></tr>
<tr><td>Working shaft diameter</td><td>2.78 mm</td><td>2.85 mm</td></tr>
<tr><td>Light source</td><td>External</td><td>Same as the subject device</td></tr>
<tr><td>Direction of view</td><td>0˚</td><td>Same as the subject device</td></tr>
<tr><td>Field of view</td><td>90˚</td><td>Same as the subject device</td></tr>
<tr><td>Viewer</td><td>Eyepiece</td><td>Same as the subject device</td></tr>
<tr><td>Distal Tip Deflection</td><td>170˚ Up
120˚ Down</td><td>285˚ Up
285˚ Down</td></tr>
</table></td></tr>
<tr><td>Non-Clinical Performance Data</td><td>Non-Clinical performance data is provided in this submission for the technical characteristics of the subject device and predicate device that differ in value. Where differences exist, the subject device test methods are equivalent to those of the predicate device. Design equivalency in optical features of the subject and predicate device supports reliance on previously submitted and cleared Optical performance test reports.

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 testing provided or referenced meets the following recognized 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:</td></tr>
</table>

	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 • FDA Guidance Document: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" <u>Reprocessing Validation Summary</u> The reprocessing data submitted and referenced complies with the following standards and guidance with regards to cleaning and sterilization: • 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

	• FDA Guidance Document: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling <u>Bench Performance Testing</u> Bench testing was performed to ensure that the device met its design specifications and is substantially equivalent to the predicate device. This testing referenced below 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 PerformanceVerification A summary of bench performance test results referenced in the submission is listed below: • Bench testing – Optical Performance Verification • Bench testing – Thermal Safety / Photobiological Safety
Clinical Performance Data	Clinical testing was not required to demonstrate the substantial equivalence to the predicate device.
Conclusion	The similarity of technological characteristics between the subject device and the predicate device supports substantial equivalence and the results of testing on the subject device support safety and effectiveness. We conclude that the substantial equivalence of the subject and the predicate device has been demonstrated, and differences between the subject and predicate device do not raise new questions of safety or effectiveness.