August 1, 2024

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

Re: K241945
Trade/Device Name: KARL STORZ Ped. Cysto-Urethro-Fiberscope (11278AC2);
KARL STORZ Ped. Cysto-Urethro-Fiberscope (11278ACU1)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB, FBO
Dated: July 2, 2024
Received: July 3, 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.

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

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)*
K241945

Device Name
KARL STORZ Ped. Cysto-Urethro-Fiberscope (11278AC2);
KARL STORZ Ped. Cysto-Urethro-Fiberscope (11278ACU1)

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.

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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:	July 2, 2024
Type of 510(k) Submission:	Special
Device Identification:	Trade Name: KARL STORZ Pediatric Cysto-Urethro-Fiberscope Models: 11278ACU1/AC2
Common Name:	Ureteroscope and Accessories
Regulatory Class:	II
Product Code:	FGB, FBO
Regulation:	876.1500 – Endoscope and accessories
Device Panel:	Gastroenterology & Urology
Predicate Device(s):	Primary Predicate Device: KARL STORZ Pediatric Flexible Cysto-Urethro-Fiberscope (Flex-X2) and Accessories 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 Numbers: 11278ACU1 and 11278AC2) 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.
Environment of Use:	The KARL STORZ Pediatric Cysto-Urethro-Fiberscope and Accessories is intended to be used only in healthcare facilities/hospitals.

<table>
<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 K082046</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>450 mm</td><td>Same as the subject device</td></tr>
<tr><td>Working shaft diameter</td><td>2.85 mm</td><td>Same as the subject device</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>285˚ Up
285˚ Down</td><td>Same as the subject device</td></tr>
</table></td></tr>
<tr><td>Non-Clinical Performance Data</td><td>Non-Clinical performance data is not provided in this submission as the majority of the technological characteristics of the subject device and predicate device are equivalent. Where differences exist, the results of testing on the reference device are leveraged in support of safety and effectiveness.</td></tr>
<tr><td>Clinical Performance Data</td><td>Clinical testing was not required to demonstrate the substantial equivalence to the predicate device.</td></tr>
<tr><td>Conclusion</td><td>The similarity of technological characteristics between the subject device and the predicate and reference devices supports substantial equivalence to the predicate device and the results of testing on the reference device are leveraged in support of 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.</td></tr>
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