June 10, 2024

Karl Storz Endovision, Inc
% Jennifer Downing
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy America, Inc
2151 E. Grand Avenue
El Segundo, California 90245

Re: K232911
Trade/Device Name: KARL STORZ Flexible Uretero-Reno-Fiberscope FLEX-X2S [positive deflection] (11278A2), STORZ Flexible Uretero-Reno-Fiberscope FLEX-X2S [contra-positive deflection] (11278AU1)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Received: May 15, 2024

Dear Jennifer Downing:

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232911

Device Name

KARL STORZ Flexible Uretero-Reno-Fiberscope FLEX-X2S [positive deflection] (11278A2);
KARL STORZ Flexible Uretero-Reno-Fiberscope FLEX-X2S [contra-positive deflection] (11278AU1)

Indications for Use *(Describe)*

The KARL STORZ Flexible Uretero-Reno-Fiberscope is indicated for examination of the upper urinary tract including the ureter and kidneys and, using additional accessories, to perform various diagnostic and therapeutic procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 Endoscopy America, Inc. 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Jennifer Downing Senior Regulatory Affairs Specialist jennifer.downing@karlstorz.com Tel.: 1-424-218-8115
Date of Preparation:	September 18th, 2023
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ Flexible Uretero-Reno-Fiberscope Models: 11278A2/AU1
Common Name:	Ureteroscope and Accessories
Regulatory Class:	II
Product Code:	FGB
Classification Name:	876.1500 - Endoscope and accessories
Device Panel:	Gastroenterology & Urology
Predicate Device(s):	Primary Predicate Device: K982905 -MVM 7.5 French Flexible Ureteroscope Secondary Predicate Device: K925128 - 11274 Series Flexible Fiberscope These predicate devices have not been subject to a design-related recall. K982905 was subject to a reprocessing-related recall, which was resolved via a labeling update to discontinue use of HLD reprocessing for the affected ureteroscopes. HLD reprocessing is <u>not</u> used for the subject device in this 510(k) submission.
Device Description:	The optical component of the KARL STORZ flexible ureteroscope consists of: • A light post connection with screw-on adapters for fiberoptic light cables.

<table>
<tr><td></td><td>• A fiber optic light conductor
• An optical image bundle behind an objective lens
• A flexible shaft housing
• A magnifying eyepiece with a focusing ring that rotates to adjust to the appropriate diopter correction for the user
• A reticle, or marker in the field of view, that indicates the 12 o’clock position as a point of reference

The insertable portion of the instrument is divided into a flexible shaft section and a deflection section. The features of the shaft include:

• A working channel that accepts flexible accessories at the proximal end and features a T-LUER Lock fitting for irrigation
• A deflection lever, for active distal tip deflection
• A proximal strain relief that connects the flexible shaft to the handpiece</td></tr>
<tr><td>Indications For Use:</td><td>The KARL STORZ Flexible Uretero-Reno-Fiberscope is indicated for examination of the upper urinary tract including the ureter and kidneys and, using additional accessories, to perform various diagnostic and therapeutic procedures.</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>Primary Predicate K982905</th><th>Secondary Predicate K925128</th></tr>
<tr><td>Type of Scope</td><td>Flexible</td><td>Same as the subject device</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><td>Same as the subject device</td></tr>
<tr><td>Working shaft length</td><td>675 mm</td><td>700 mm</td><td>400, 600, 800 mm</td></tr>
<tr><td>Working shaft diameter</td><td>2.85 mm</td><td>Same as the subject device</td><td>2.79 mm</td></tr>
<tr><td>Light source</td><td>External</td><td>Same as the subject device</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><td>Same as the subject device</td></tr>
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<tr><td>Field of View</td><td>90º</td><td>Same as the subject device</td><td>70º</td></tr>
<tr><td>Viewer</td><td>Eyepiece</td><td>Integrated Video Module</td><td>Same as the subject device</td></tr>
<tr><td>Distal Tip Deflection</td><td>285º Up
285º Down</td><td>120º Up
170º Down</td><td>120º Up
120º Down</td></tr>
</table>
</td></tr>
<tr><td>Non-Clinical Performance Data:</td><td>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:

<u>Biocompatibility testing</u>
The system complies with the following standards:
• ISO 10993

<u>Reprocessing Validation Summary</u>
The reprocessing data submitted complies with the following standards and guidance with regards to cleaning and sterilization:
• AAMI ST91:2021
• ANSI/AAMI/ISO 14937:2009
• FDA Guidance Document Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Additional bench testing was performed to ensure that the device met its design specifications and is substantially equivalent to its predicate devices. This data complies with the following standards:
• IEC 60601-2-18:2009
• IEC 62471:2006
• ISO 8600-5:2020</td></tr>
<tr><td>Clinical Performance Data:</td><td>Clinical testing was not required to demonstrate the substantial equivalence to the predicate device. Non-clinical bench testing was sufficient to assess safety and effectiveness and to establish the substantial equivalence of the modifications.</td></tr>
<tr><td>Conclusion:</td><td>The conclusions drawn from the nonclinical tests demonstrate that the</td></tr>
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	subject device, the KARL STORZ Flexible Uretero-Reno-Fiberscope, performs as well as or better than the predicate devices that are currently marketed for the same intended use.