September 3, 2021

KARL STORZ Endoscopy America, Inc.
Thomas Ostrowski
Senior Regulatory Affairs Specialist
2151 E. Grand Ave
El Segundo, CA 90245

Re: K212476
Trade/Device Name: Flexible HD Cysto-Urethroscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FAJ, FBO
Dated: August 5, 2021
Received: August 6, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K212476

Device Name
Flexible HD Cysto-Urethroscope System

Indications for Use *(Describe)*
The Flexible HD Cysto-Urethroscope System is used to provide visualization and operative access during diagnostic and therapeutic endoscopic procedures of urinary tract including the urethra, bladder, ureters, and kidneys.

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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8. 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.

Applicant:	KARL STORZ Endoscopy-America, Inc 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Thomas Ostrowski Senior Regulatory Affairs Specialist 781-910-8508 (phone)
Date of Preparation:	August 27th, 2021
Type of 510(k) Submission:	Special
Device Identification:	Trade Name: Flexible HD Cysto-Urethroscope System
Common Name:	Cystoscope and accessories, Flexible/Rigid (FAJ) Cystourethroscope (FBO)
Product Code:	FAJ, FBO
Regulation Name / Number:	Endoscope and Accessories (21 CFR 876.1500)
Predicate Device(s):	Flexible HD Cysto-Urethroscope System (K191357) – Primary Flexible Video Cysto-Urethroscope (C-View) (K202957) – Secondary ***The above predicate devices have not been subject to any recall***

<table>
<tr><td>Device Description:</td><td>The Flexible HD Cysto-Urethroscope System (Part Number: 11272VH(U)-TL) is intended to be used with the IMAGE1 S CCU consisting of Connect / Connect II and X-Link modules (cleared in K201135). Identical to the predicates, the scope cannot be operated on its own because it produces image data output in the form of video signals which require external processing and display. When the scope is used with the compatible CCU, it becomes the Flexible HD Cysto-Urethroscope System, which can then be operated as intended and indicated.

The Flexible HD Cysto-Urethroscope System consists of the following key components:
• 11272VH-TL / 11272VHU-TL – Cysto-Urethroscopes with positive (VH-TL) / contra-positive (VHU-TL) deflection control and permanent T-Luer affixed to working channel
• TC200US / TC201US / TC301US – Connect/Connect II/Link camera control unit (CCU) modules for image processing

The subject device is a lower cost alternative to the primary predicate and incorporates the following differences.

• Housing Plug: Due to lack of clinical need, the subject device replaces the suction channel of the primary predicate device with a permanent stainless steel housing plug.
• Fixed LUER: The subject device uses a removable T-Luer whereas the primary predicate supported a removable T-Luer or Stopcock.</td></tr>
<tr><td>Intended Use and Indications for use:</td><td>The Flexible HD Cysto-Urethroscope System is used to provide visualization and operative access during diagnostic and therapeutic endoscopic procedures of urinary tract including the urethra, bladder, ureters, and kidneys.
The minor modifications to the Flexible HD Cysto-Urethroscope System do not change the intended use and indications for use. The intended use / indications for use are identical between the proposed device and the predicate devices.</td></tr>
<tr><td>Technological Characteristics:</td><td>The subject device is a modification of the primary predicate, 11272VH/VHU, cleared via K191357 and also incorporates design features of the secondary predicate device, 11272VE/VUE, cleared via K202957. A comparison between the proposed device and primary predicate device is included in the table below:

<table>
<tr><th></th><th>Proposed Device</th><th>Primary Predicate K191357</th><th>Secondary Predicate K202957</th></tr>
<tr><th colspan="4">Physical Characteristics</th></tr>
<tr><td>Type of scope</td><td>Flexible</td><td>Same</td><td>Same</td></tr>
<tr><td>Insertion Shaft Diameter</td><td>5.5 mm</td><td>Same</td><td>5.2 mm</td></tr>
</table>
</td></tr>
</table>

Insertion Shaft Length	37 cm	Same	Same
Working Channel Diameter	2.3 mm	Same	Same
Deflection (°)	Up: 210^0 Down: 140^0	Same	Same
Optical Characteristics			
Type of Imager	CMOS	Same	Same
Field of View	100^0	Same	Same
Direction of View	0^0	Same	Same
Depth of Field	3-50 mm	Same	5-50 mm
On-axis Resolution (minimal)	40 lp/mm @ 3 mm 2.5 lp/mm @ 50 mm	Same	16 lp/mm @ 5 mm 1.8 lp/mm @ 50 mm
Light Source	Internal LED	Same	Same
Material / Design Characteristics			
Suction Port / Channel	No	Yes	No
Luer Type	Permanent T-Luer	Bayonet with removable T-Luer or Stopcock assembly	Same as proposed device
Cleaning, Disinfection and Sterilization Methods			
Cleaning	Manual	Same	Same
Sterilization	STERRAD 100NX (FLEX and DUO cycles), STERRAD NX (Advanced Cycle), V-PRO maX (Flexible Cycle), V-PRO 60	Same with additional support for SS1E (Standard Cycle)	Same as proposed device
High Level Disinfection	Revital-Ox RESERT	Same	Same

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 FDA recognized consensus standards identified in the primary and secondary predicate device submissions:

- Electrical Safety and EMC
  - IEC 60601-1:2005/(R)2012, Ed. 3.1
  - IEC 60601-1-2:2014, 4th Ed.
  - IEC 60601-2-18:2009, Ed. 3.0
- Optical/Mechanical Performance
  - IEC 62471:2006
  - ISO 8600

	• Biocompatibility
	  ○ ISO 10993-1:2009/(R) 2013
	  ○ ISO 10993-5:2009/(R) 2014
	  ○ ISO 10993-10:2010
	  ○ ISO 10993-11:2006/(R) 2010
	• Reprocessing
	  ○ AAMI TIR 12:2010
	  ○ ISO 15883-5:2005
	  ○ AAMI TIR 30:2011
	  ○ AAMI/ANSI/ISO 11737-1:2006/ (R)2011
	  ○ ASTM E1837-96:2014

Substantial Equivalence:	The intended use, operating principles, technological characteristics and features are similar, if not identical, between that subject device and the predicate devices, Flexible HD Cysto-Ureteroscope System (K191357) and Flexible Video Cysto-Uretheroscope (C-View) (K202957). The minor difference between the subject and predicate devices that does not raise new or different questions or safety and effectiveness are listed above in Technological Characteristics section. As proven by the comparisons, the differences do not raise different questions of safety and effectiveness because the intended use, operating principles, technological characteristics, and features are similar, if not identical. Both systems also comply with identical standards and safety testing, where applicable. Substantial equivalence to the effectiveness of the subject device is supported by the comparison of the images and standard image quality characteristics including, but not limited to the performance testing listed above.
Clinical Performance Data:	Clinical performance is not required to demonstrate substantial equivalence to the predicate devices. Comparative analysis is sufficient to establish substantial equivalence.
Conclusion:	The Flexible HD Cysto-Urethroscope System is substantially equivalent to its predicate devices. The comparative analysis demonstrates that the device is as safe and effective as the legally marketed devices.