September 18, 2019

KARL STORZ Endoscopy-America, Inc.
Irina Fedorov
Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K191357
Trade/Device Name: Flexible HD Cysto-Urethroscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FAJ, FBO
Dated: August 14, 2019
Received: August 19, 2019

Dear Irina Fedorov:

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,

Sharon M. Andrews
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191357

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

7. 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.

KARL-STORZ Endoscopy-America is submitting this 510(k) to seek clearance for a change to add Sterilization V PRO-60 and High Level Disinfection (HLD) for the currently cleared Flexible HD Cysto-Urethroscope System (K182723). This submission is traditional 510(K) as since we are including two reports to supports the additions.

Submitter:	KARL STORZ Endoscopy-America, Inc. 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Irina Fedorov Regulatory Affairs Specialist Phone: (508) 248-1275 Fax: (508) 248-9017
Date of Preparation:	May 17, 2019
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: HD View Common Name: Flexible HD Cysto-Urethroscope System Classification Name: Endoscope and accessories (21 CFR Part 876.1500)
Regulatory Class:	II
Product Code:	FAJ, FBO
Guidance Document:	Not Applicable for FAJ/FBO product codes
Recognized Consensus Standards:	Not Applicable for FAJ/FBO product codes
Predicate Device(s):	Predicate Device: KARL STORZ Flexible HD Cysto-Urethroscope (K182723)
Device Description:	The components subject of this submission are: the Flexible HD Cysto-Urethroscope (Part Number: 11272VH(U)), the LUER ports (Part

<table>
<tr><td></td><td>Number: 11014L(U)), the Suction Valve (Part Number: 11301CE1/20), and the IMAGE1 S CCU. The CCU consists of the IMAGE1 S Connect Module (Model Number: TC200US) and IMAGE1 S X-Link (Model Number: TC301US).</td></tr>
<tr><td>Intended Use:</td><td>The Flexible HD Cysto-Urethroscope System is intended for visualization purposes during urological diagnostic and therapeutic procedures.</td></tr>
<tr><td>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.</td></tr>
<tr><td>Technological Characteristics:</td><td>
<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device, K182723</th></tr>
<tr><th colspan="3">Cleaning and Sterilization Methods</th></tr>
<tr><td>Cleaning</td><td>Manual</td><td>Same as the subject device</td></tr>
<tr><td>Sterilization</td><td>• STERRAD 100NX (FLEX and DUO Cycles)
• STERRAD NX (Advanced Cycle)
• V-PRO maX (Flexible Cycle)
• SS1E (Standard Cycle)
• V-PRO 60</td><td>• STERRAD 100NX (FLEX and DUO Cycles)
• STERRAD NX (Advanced Cycle)
• V-PRO maX (Flexible Cycle)
• SS1E (Standard Cycle)</td></tr>
<tr><td></td><td>• Resert XL</td><td>• None</td></tr>
</table>
</td></tr>
<tr><td>Non-Clinical Performance Data:</td><td>Biocompatibility Summary
The biocompatibility evaluation for the patient contacting components of the neuroscope was performed according to ISO 10993-1 and FDA Guidance. The following tests were conducted based contact type and duration:
• ISO 10993-5:2009/(R) 2014
• ISO 10993-10:2010
• ISO 10993-11:2006/(R) 2010

Reprocessing Validation Summary
The Flexible HD Cysto-Urethroscope (Part Number: 11272V(H)) is provided non-sterile and is reusable. The users are required to reprocess it for initial and after each use. The subject device contacts intact mucosal membranes so it is a semi-critical device per Spaulding Classification. We performed validation activities for cleaning, sterilization and HLD according to the FDA Guidance. The reprocessing data submitted is in compliance with the following standards:
• AAMI TIR 12:2010
• ISO 15883-5:2005
• AAMI TIR 30:2011
• AAMI/ANSI/ISO 11737-1:2006/ (R)2011</td></tr>
</table>

	• ASTM E1837-96:2014
Clinical Performance Data:	Clinical testing was not required to demonstrate the substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to establish the substantial equivalence of the modifications.
Conclusion:	The conclusions drawn from the nonclinical tests demonstrate that the subject device, the Flexible HD Cysto-Urethroscope System performs as well as or better than the legally marketed predicate device.