April 23, 2019

KARL STORZ Endoscopy-America, Inc.
Nozomi Yagi, MAS, RAC
Sr. Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K182723
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: March 13, 2019
Received: March 14, 2019

Dear Nozomi Yagi:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K182723

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.

Submitter:	KARL STORZ Endoscopy-America, Inc. 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Nozomi Yagi Sr. Regulatory Affairs Specialist Phone: (424) 218-8351 Fax: (424) 218-8519
Date of Preparation:	April 10, 2019
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: Flexible HD Cysto-Urethroscope System Classification Name: Endoscope and accessories (21 CFR Part 876.1500)
Regulatory Class:	II
Product Code:	FAJ (Cystoscope and accessories, flexible/rigid) FBO (Cystourethroscope)
Guidance Document:	Not Applicable for FAJ/FBO product codes
Recognized Consensus Standards:	Not Applicable for FAJ/FBO product codes
Predicate Device(s):	Primary Predicate Device: Olympus Corporation of the America's VISERA Cysto-Nephroscope (K133538) Secondary Predicate Device: KARL STORZ Endoscopy-America's Flexible CMOS-Video-Cysto-Urethroscope (K131364)
Device Description:	The components subject of this submission are: the Flexible HD Cysto-Urethroscope (Part Number: 11272VH(U)), the LUER ports (Part Number: 11014L(U)), the Suction Valve (Part Number: 091011-20), and the IMAGE1 S CCU. The CCU consists of the

<table>
<tr><td></td><td>IMAGE1 S Connect Module (Model Number: TC200US) and IMAGE1 S X-Link (Model Number: TC301US).

The Flexible HD Cysto-Urethroscope (Part Number: 11272VH(U)) is a reusable, flexible video scope with an insertion shaft OD of 5.5 mm and length of 37 cm, a working channel OD of 2.3 mm, and a suction channel. Users can choose to attach either a LUER port with stopcocks (Part Number: 11014L) or a double LUER port (Part Number: 11014LU) to the working channel port. In terms of optics, it has direction of view of 0° and field of view of 100°.</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>Comparison Table: Subject vs. Primary and Secondary Predicate Devices
<table>
<tr><th></th><th>Subject Device</th><th>Primary Predicate Device, K133538</th><th>Secondary Predicate Device, K131364</th></tr>
<tr><th colspan="4">Physical Characteristics</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>Insertion Shaft Diameter</td><td>5.5 mm</td><td>Same as the subject device</td><td>Same as the subject device</td></tr>
<tr><td>Insertion Shaft Length</td><td>37 cm</td><td>38 cm</td><td>Same as the subject device</td></tr>
<tr><td>Deflection</td><td>210° Up, 140° Down</td><td>220° Up, 130° Down</td><td>Same as the subject device</td></tr>
<tr><th colspan="4">Optical Characteristics</th></tr>
<tr><td>Type of Imager</td><td>CMOS</td><td>CCD</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>
<tr><td>Light Source</td><td>Internal LED</td><td>External Xenon</td><td>Same as the subject device</td></tr>
<tr><th colspan="4">Cleaning and Sterilization Methods</th></tr>
<tr><td>Cleaning</td><td>Yes</td><td>Same as the subject device</td><td>Same as the subject device</td></tr>
<tr><td>Sterilization</td><td>Yes</td><td>Same as the subject device</td><td>Same as the subject device</td></tr>
</table></td></tr>
<tr><td>Non-Clinical Performance Data:</td><td>Electrical Safety and Electromagnetic Compatibility Summary
The electrical safety and EMC data included in the submission is in compliance with the following FDA recognized standards:
• ANSI/AAMI ES:60601-1:2005
• IEC 60601-1-2:2007

Bench Testing Summary</td></tr>
</table>

	The performance data submitted in the submission is in compliance with the following FDA recognized standards: • IEC 62471:2006 **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 and sterilization 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 • 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 devices.