September 1, 2020

Karl Storz Endoscopy-America, Inc.
Alita McElroy
Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K201135
Trade/Device Name: Image1 S CCU (TC200US, TC201US, TC300US, TC301US, TC302US, TC304US); Image1 S 4U Camera Head (TH120)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Dated: July 31, 2020
Received: August 3, 2020

Dear Alita McElroy:

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,

For Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant 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)*
K201135

Device Name
Image1 S CCU (TC200US, TC201US, TC300US, TC301US, TC302US, TC304US)
Image1 S 4U Camera Head (TH120)

Indications for Use *(Describe)*
The Image1 S is a camera control unit (CCU) for use with camera heads or video endoscopes for the visualization, image recording and documentation during general endoscopic and microscopic procedures.
The Image1 S 4U camera head is intended to be attached to the Image1 S Camera Control Unit (CCU) and compatible endoscope for visualization, image recording and documentation during general endoscopic and microscopic procedure.

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 KSEA's knowledge.

Submitter:	KARL STORZ Endoscopy-America, Inc. 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Alita McElroy Regulatory Affairs Specialist Phone: (424) 218-8376 Fax: (424) 218-8519
Date of Preparation:	September 1, 2020
Type of 510(k) Submission:	Traditional
Device Name: (Model numbers)	Image1 S CCU (TC200US, TC201US, TC300US, TC301US, TC302US, TC304US) Image1 S 4U Camera Head (TH120)
Common Name:	Endoscopic Video Imaging System/Component
Regulation Number:	21CFR 876.1500
Regulation Name:	Endoscope and Accessories
Regulatory Class:	II
Product Code:	FET
Product Code Name	Endoscopic Video Imaging System/Component
Device Panel:	Gastroenterology/Urology
Predicate Device(s):	Image1 S (K160044)
Device Description:	The Image1 S camera control unit is a medical device which consists of the Image1 S Connect (TC200US), Image1 S Connect II (TC201US) modules and the link modules. The link modules are Image1 S H3-Link (TC300US), Image1 S X-Link (TC301US), Image1 S D3-Link (TC302US) and Image1 S 4U-Link (TC304US).

	The Image1 S Connect (TC200US) and the Image1 S Connect II (TC201US) modules can be connected to a minimum of one and a maximum of three links modules. The modularity enables customers to customize their Image1 S system to their specific current and future video needs. The Image1 S includes, but not limited to, the following features: • Brightness control • Enhancement Control • Automatic Light Source Control • Shutter Control • Image/Video Capture When the Image1 S Connect II module is used with the 4U-Link and the Image1 S 4U camera head, it can output a 4K image to the monitor and also offers 7 increments of zoom ranging from 1x to 2.5x. The software version of the Image1 S camera control is upgraded to version 4.0. Software version 4.0 introduces the KS HIVE, an Ethernet based interface that allows for communication between the Image 1 S camera control unit and certain KARL STORZ devices.
Intended Use and Indications for Use:	The Image1 S is a camera control unit (CCU) for use with camera heads or video endoscopes for visualization, image recording and documentation during general endoscopic and microscopic procedures. The Image1 S 4U camera head is intended to be attached to the Image1 S Camera Control Unit (CCU) and compatible endoscope for visualization, image recording and documentation during general endoscopic and microscopic procedure.
Technological Characteristics:	The Image1 S camera control unit consists of the Image1 S Connect (TC200US), Image1 S H3-Link (TC300US), Image1 S X-Link (TC301US) cleared in K131953 and the Image1 S D3-Link (TC302US) cleared in K150525 The modified Image1 S now includes following additional components: • Image1 S Connect II (TC201US) • Image1 S 4U-Link (TC304US) • Image1 S 4U Camera Head (TH120) The following comparison table summarizes the technological characteristics between the subject and predicate devices:

	Technological Characteristics		Image1 S Subject Device	Image1 S Predicate Device K160044
	Camera Head	**Imager Type**	CMOS	CMOS
		Sensor Resolution	3840 x 2160p	1920 x 1080p
	Camera Control Unit	**Zoom**	1x, 1.2x, 1.5x, 1.75x, 2x, 2.25x, 2.5x	1x, 1.2x, 1.5x, 1.75x, 2x
		Adaptive Zoom	Yes	No
		Digital Outputs	12G/3G-SDI DisplayPort DVI-D	3G-SDI DVI-D
		Software version	4.0	2.4
		Communication Interface	KS HIVE	SCB
	Comparative testing of optical parameters and software verification and validation testing demonstrated that the subject device is as safe and as effective as the predicate device.			
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 Image1 S follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance: • Electrical Safety and EMC o IEC 60601-1:2012 (3rd Edition)- Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance o IEC 60601-1-2:2014 (4th Edition)- Medical Electrical Equipment - Part 1- 2: General Requirements for Basic Safety and Essential Performance – Collateral Standard:			

	Electromagnetic Compatibility - Requirements and Tests o IEC 60601-2-18:2009 (3rd Edition) – Medical Electrical Equipment Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment • Software Verification and Validation Testing o Guidance for the Content of Premarket Submissions for Software Contained in Medical Device o Level of concern: Moderate Cleaning and sterilization validations were conducted for the Image1 S 4U camera head. The reprocessing data submitted is in compliance with the following standards: • ANSI/AAMI/ISO 14937:2009/(R) 2013 • AAMI TIR 12:2010 • ANSI/AAMI ST81:2004/(R) 2010 • ANSI/AAMI ST79: 2010/A4:2013 • ANSI/AAMI ST 58:2005 • ANSI/AAMI/ISO 14161:2000 Additional bench testing was performed to ensure the device met its design specifications. The bench testing performed verified and validated that the Image1 S has met all its design specification and is substantially equivalent to its predicate device.
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.
Substantial Equivalence:	The conclusions drawn from the cleaning and sterilization, software, electrical safety and EMC as well as bench top performance tests demonstrated that the subject device is as safe and as effective as the predicate device. As such, we concluded that the substantial equivalence of the subject and the predicate device has been met, and the differences between the subject and predicate do not raise new questions of safety and effectiveness.