June 23, 2022

Karl Storz Endoscopy America, Inc.
Alita McElroy
Senior Regulatory Affairs Specialist
2151 E. Grand Ave
El Segundo, California 90245

Re: K213194
Trade/Device Name: HD Mediastinoscope
Regulation Number: 21 CFR 874.4720
Regulation Name: Mediastinoscope And Accessories
Regulatory Class: Class II
Product Code: EWY
Dated: May 31, 2022
Received: June 2, 2022

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 Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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)*
K213194

Device Name
HD Mediastinoscope

Indications for Use *(Describe)*
The HD Mediastinoscope is intended to aid the surgeon in viewing the mediastinum and facilitate the introduction and removal of surgical instruments during ENT endoscopic surgical 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.

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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 Senior Regulatory Affairs Specialist Phone: (424) 218-8376 Email: Alita.McElroy@karlstorz.com
Date of Preparation:	June 23, 2022
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: HD Mediastinoscope Classification Name: Mediastinoscope and accessories (21 CFR 874.4720)
Regulatory Class:	II
Product Code:	EWY
Classification Panel:	ENT
Predicate Device(s):	Predicate Device: Optical Mediastinoscope (K954910) Reference Devices: HOPKINS I & II Rigid Autoclavable Telescope (K935279), C- cam (K143640), HD Mediastinoscope (K202272)
Device Description:	The HD Mediastinoscope is a reusable videoendoscope intended to be used in conjunction with the X-link module of the Image1 S Camera Control Unit. The HD Mediastinoscope is comprised of four main components: CMOS sensor at the distal end of the endoscope, an oval insertion portion (spatula), handle, and internal LED light source. The spatula can accommodate up to 2 x 5 mm instruments.
Intended Use:	The HD Mediastinoscope System is intended for visualization purposes during surgical procedures.
Indications for Use:	The HD Mediastinoscope is intended to aid the surgeon in viewing the mediastinum and facilitate the introduction and removal of surgical instruments during ENT endoscopic surgical procedures.
Technological Characteristics.	The subject device, HD Mediastinoscope is substantially equivalent to the KARL STORZ Optical Mediastinoscope, (510(k) Number: K954910), marketed by KARL STORZ Endoscopy-America. The Hopkins telescope (K935279) and C-cam (K143640) were chosen as reference devices to be used with the predicate to support optical characteristics as they are required to be used with the predicate for a

	complete imaging system. The subject and predicate devices have the same intended use, indications for use, similar technological and optical characteristics. The main differences between the subject and the predicate devices include the following: • The subject device is a videoendoscope equipped with an internal light source and CMOS sensor chip whereas the predicate is an optical mediastinoscope that requires connection to external components (Hopkins telescope, camera head, light source) • The insertion shaft diameter, field of view and on-axis resolution are slightly different when compared to the predicate device • The distal tip spatula radius of the subject device is different when compared to the predicate device The subject device is a modification of the reference device, HD Mediastinoscope (510(k) Number: K202272), marketed by KARL STORZ Endoscopy-America. The difference between the subject device and the reference is that the subject device has a rounded spatula edge with an increased distal tip spatula radius of 5mm +2/-1mm and wall thickness of 1.2mm 0/-0.25mm in comparison to the cleared device with a sharp spatula edge, distal tip spatula radius of 1mm and spatula wall thickness of 0.77mm. The cleared HD Mediastinoscope (510(k) Number: K202272) has been chosen as reference device to leverage previous testing such as optical performance tests, electrical safety, biocompatibility and reprocessing to demonstrate safety and effectiveness of the subject device when compared to the predicate device.
Non-Clinical Performance Data:	The subject device, HD Mediastinoscope is compliance with the following FDA recognized standards: Electrical Safety and EMC • ANSI/AAMI ES:60601-1:2005+A1:2012 • IEC 60601-1-2:2014 • IEC 62471:2006 Biocompatibility • ISO 10993-10:2010 • ISO 10993-11:2006/(R) 2010 Reprocessing Validation Summary • AAMI TIR 12:2010 • AAMI TIR 30:2011 • AAMI/ANSI/ISO 11737-1:2006/ (R)2011 ASTM E1837-96:2014 A cadaver test study was conducted to demonstrate that the change in spatula design of the subject device does not raise new questions of safety and effectiveness when

	compared to the predicate device and the reference 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 subject device to the predicate device.
Conclusion:	The nonclinical test demonstrate that the subject device is substantially equivalent to the predicate device.