May 11, 2021

Karl Storz Endoscopy America, Inc.
Winkie Wong
Manager, Regulatory Affairs
2151 E. Grand Ave
El Segundo, California 90245

Re: K202272
Trade/Device Name: HD Mediastinoscope
Regulation Number: 21 CFR 874.4720
Regulation Name: Mediastinoscope And Accessories
Regulatory Class: Class II
Product Code: EWY
Dated: April 2, 2021
Received: April 8, 2021

Dear Winkie Wong:

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 to pic. 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
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)*
K202272

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:	Winkie Wong Manager, Regulatory Affairs Phone: (424) 218-8379 Email: Winkie.wong@karlstorz.com
Date of Preparation:	May 3rd, 2021
510K Number	K202272
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):	Optical Mediastinoscope (K954910) - Predicate Hopkins I & II Rigid Autoclavable Telescope (K935279) – Reference C-cam (K143640) – Reference ***The above predicate and reference devices have not been subjected to any recall***
Device Description:	The components subject of this submission are: HD Mediastinoscope (Part Number: 10973HD), 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).
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:

Comparison Table: Subject vs. Predicate Devices

	Subject Device	Predicate Device K954910
Physical Characteristics		
Type of Scope	Rigid	Rigid
Insertion Shaft Diameter	20 mm	25 mm
Insertion Shaft Length	18 cm	17 cm
Working Channel	1 instrument channel (for up to 2x 5mm instrument)	•1 instrument channel (for up to 2x 5mm instrument) •1 telescope channel
Optical Characteristics		
Type of Imager	CMOS	CCD (via camera head)
Direction of View	30°	Same as the subject device
Light Source	Internal LED	External
Depth of Field	18 – 50 mm	Same as subject device
Reprocessing Methods		
Cleaning	Manual	Same as the subject device
Sterilization	Yes	Yes

The Hopkins telescope (K935279) and C-cam (K143640) were chosen as reference devices to be used with the predicate to support scientific methodology during the comparison of optical characteristics.

Non-Clinical Performance Data:

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+A1:2012
- IEC 60601-1-2:2014

Bench Testing Summary
The performance data submitted in the submission is in compliance with the following FDA recognized standards:

- IEC 62471:2006

Optical Performance Testing:

- Color Reproduction and Color Contrast
- Illumination Detection Uniformity
- Instantaneous Dynamic Range (IDR) & Detection Linearity
- Spatial Resolution & Depth of Field
- Distortion & Field of view

Biocompatibility Summary
The biocompatibility evaluation for the patient contacting components of the HD Mediastinoscope 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 HD Mediastinoscope (Part Number: 10973HD) 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 • 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 HD Mediastinoscope system is substantially equivalent to the legally marketed predicate device.