



March 2, 2026

Karl Storz SE & CO.KG
Jordan Verla
Senior Regulatory Affairs Specialist
Dr.-Karl-Storz-Straße 34
Baden-Wurttemberg
Tuttlingen, 78532
Germany

Re: K260003

Trade/Device Name: KARL STORZ Mediastinoscopes and Instruments
Regulation Number: 21 CFR 874.4720
Regulation Name: Mediastinoscope And Accessories
Regulatory Class: Class II
Product Code: EWY
Dated: December 31, 2025
Received: January 2, 2026

Dear Jordan Verla:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

SHUCHEN PENG -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260003

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Please provide the device trade name(s).

?

KARL STORZ Mediastinoscopes and Instruments

Please provide your Indications for Use below.

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For devices (10970A, 10970B, 10970DS, 10973HD)

Intended to aid the surgeon in viewing the mediastinum and facilitate the introduction and removal of surgical instruments during endoscopic surgical procedures in adults and pediatric patients ≥ 12 years of age.

For devices (10900GO, 10900GP, 10900GR, 10900M, 10900MO, 10900MP, 10970, 10970GO, 10970GOL, 10970GP, 10970GPL, 10970GR, 10970GRL, 10970H, 10970K, 10970M, 10970ML)

The instruments are intended for lymph node biopsy, removal of lymphatic nodes and tumors, grasping and dissecting tissue for diagnosis and treatment of pleural, parenchymal and mediastinal disease in adults and pediatric patients ≥ 12 years of age.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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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 SE & CO. KG Dr.-Karl-Storz-Straße 34 TUTTLINGEN, Baden-Württemberg GERMANY, 78532
Contact:	Jordan Lydia Verla Senior Regulatory Affairs Specialist Tel: (424) 218-8100 ext. 8382 Email: Jordan.Verla@karlstorz.com
Date of Preparation:	December 31, 2025
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ Mediastinoscopes and Instruments Classification Name: 21 CFR 874.4720 (Mediastinoscopes and Accessories)
Regulatory Class:	II
Product Code:	EWY
Classification Panel:	Ear Nose & Throat
Predicate Device(s):	KSEA Optical Mediastinoscope for ENT (K954910) Optical Mediastinoscope with Plug-in Connection/Ocular Eyepiece (K971166) HD Mediastinoscope (K213194)
Device Description:	The Mediastinoscopes and Instruments submitted in this 510(k) consist of two (2) variants of mediastinoscope devices and compatible instruments relative to either variant: 1) Mediastinoscopes and Adaptor: 10970A, 10970B with optional adapter 10970DS and 2) HD Mediastinoscope: 10973HD 3) Forceps:

- a. Forceps inserts: 10900GO, 10900GP, 10900GR, 10900M, 10900MO, 10900MP
- b. Outer sheath: 10970
- c. Biopsy Forceps: 10970GO, 10970GOL, 10970GP, 10970GPL, 10970GR, 10970GRL, 10970H
- d. Sponge and Dissecting Forceps: 10970K, 10970M, 10970ML

MEDIASTINOSCOPIES AND ADAPTOR

The surgical stainless steel mediastinoscopes (10970A, 10970B) are non-powered, reusable surgical instruments consisting of a compact handle integrated with a rigid sheath terminating in a spatula-shaped (beveled) distal geometry to provide access to and visualization of the mediastinum and a working channel for atraumatic entry of surgical instrumentation. They rely on externally connected optical and illumination components for visualization and contain no active electronic components.

Visualization may be accomplished either via

- 1) A light carrier inserted into the mediastinoscopes and connected to an external light source for direct visualization of the surgical field or
- 2) A surgical stainless steel adaptor (10970DS) attached to the proximal end of the sheath, enabling insertion of a compatible rigid telescope into the mediastinoscopes, which is connected to an external light source and compatible camera heads and control unit (CCU) to provide video visualization of the surgical field.

Note: The mediastinoscopes are a non-spreadable design and may be used with a light carrier.

HD MEDIASTINOSCOPE

(Identical to the HD Mediastinoscope 10973HD cleared under K213194)

The HD Mediastinoscope (10973HD) is comprised of four main components: a CMOS sensor located at the distal end of the endoscope, an oval insertion portion (spatula), a handle, and an internal LED light source. The subject device is unchanged in design, materials, dimensions, optical characteristics, and illumination performance when compared to the HD Mediastinoscope (10973HD) cleared under K213194.

The only difference between the subject device and the cleared device is an expansion of the indicated patient population to include adolescents ≥ 12 years of age.

	<p>INSTRUMENTS</p> <p>The KARL STORZ Mediastinoscopes and Instruments, including forceps and accessories, are manually operated, reusable surgical devices intended for lymph node biopsy, removal of lymphatic nodes and tumors, grasping and dissecting tissue for diagnosis and treatment of pleural, parenchymal and mediastinal disease in adults and pediatric patients ≥ 12 years of age.</p> <p>Forceps and sheaths are integral accessories that enable the mediastinoscope to perform its intended diagnostic and therapeutic functions. Sheaths provide a protective channel and maintain visualization while allowing instrument passage, whereas forceps deliver essential capabilities for grasping, cutting, and biopsy of tissue. In combination these instruments complement the mediastinoscope design by facilitating safe tissue manipulation and sampling without requiring additional incisions, ensuring the system operates as a complete solution for mediastinal, pleural, and parenchymal procedures.</p>
<p>Indications for Use:</p>	<p><u>For devices (10970A, 10970B, 10970DS, 10973HD)</u></p> <p>Intended to aid the surgeon in viewing the mediastinum and facilitate the introduction and removal of surgical instruments during endoscopic surgical procedures in adults and pediatric patients ≥ 12 years of age.</p> <p><u>For devices (10900GO, 10900GP, 10900GR, 10900M, 10900MO, 10900MP, 10970, 10970GO, 10970GOL, 10970GP, 10970GPL, 10970GR, 10970GRL, 10970H, 10970K, 10970M, 10970ML)</u></p> <p>The instruments are intended for lymph node biopsy, removal of lymphatic nodes and tumors, grasping and dissecting tissue for diagnosis and treatment of pleural, parenchymal and mediastinal disease in adults and pediatric patients ≥ 12 years of age.</p>
<p>Technological Characteristics:</p>	<p>The HD Mediastinoscope has been compared to legally marketed HD Mediastinoscope (K213194). The subject and predicate device (K213194) have identical technological and physical characteristics, and identical operating principles as the subject device.</p> <p>The Mediastinoscopes and Adaptor has been compared to legally marketed predicate KSEA Optical Mediastinoscope for ENT (K954910) and the Instruments have been compared to legally marketed predicate Richard Wolf Optical Mediastinoscope with Plug-in Connection/Ocular Eyepiece (K971166):</p> <p>The subject and predicate devices (K954910, K971166) have similar technological and physical characteristics, with some variations in</p>

dimensions that are considered minor (see Table below). Furthermore, performance testing shows that the design of the present submission's subject devices are suitable for the claimed intended use.

	KARL STORZ Mediastinoscopes and Instruments Subject Device Mediastinoscopes and Adaptor	KSEA Optical Mediastinoscope for ENT (K954910) Predicate Device for Mediastinoscopes and Adaptor
Type of Scope	Access sheath (no optical function)	Same as the subject
Insertion Shaft Diameter	10970A/B Beveled design (oval) Width: 22mm Height: 17mm	Beveled design (oval) 15mm
Insertion Shaft Length	10970A 13cm 10970B 17cm	17cm
Working Channel	10970A/B - oval lumen - min. width 11.35mm - height 14mm - for two 5mm instruments	Same as the subject
Distal Tip Spatula Radius	10970A/B 45°	Not applicable as the slit that generates the radius is not present
Spatula Edge	10970A/B Rounded	Same as the subject
Wall Thickness	10970A/B 1mm	10970A / 10970B 0.93-0.97mm
Interface light carrier	Interface for connection of light carrier	Same as the subject
Interface for Adapter	Interface for connection Adaptor 10970DS	Telescope adaptor integrated

	KARL STORZ Mediastinoscopes and Instruments Subject Device Instruments	Richard Wolf Optical Mediastinoscope with Plug-in Connection/Ocular Eyepiece (K971166) Predicate Device for Instruments
Working Length	20-30cm	24-31cm
Outer Diameter	5mm-8.6mm	3.5mm
Handle	Pistol handle (without ratchet)	Same as the subject
Jaws	Cutting Grasping	Cutting
Jaw Articulation	Single-action Double-action	Single-action Double-action
Shaft Design	Sliding shaft Tube shaft Medial joint	Tube shaft Medial joint
Suction Channel	10970H Yes, with inner diameter 3.4 mm	No
Outer Sheath	10970	Not Available
Overall Length	21 cm	
Outer Sheath Outside Diameter	10970 5 mm	Not Available
Non-Clinical Performance Data:	<p>There are no performance standards or special controls developed under Section 514 of the FD&C Act for endoscopes. However, the subject device follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance:</p> <p>Risk</p> <ul style="list-style-type: none"> • ISO 14971:2019 <p>Software</p> <ul style="list-style-type: none"> • IEC 62304 (<i>Applicable only to 10973HD</i>) <p>Usability</p> <ul style="list-style-type: none"> • IEC 62366-1:2015 + Amd.1:2020 <p>Photobiological Safety</p> <ul style="list-style-type: none"> • IEC 62471:2006 	

Endoscope (Optical)

- ISO 8600-1 (*Applicable only to 10973HD*)

Biocompatibility Summary

- Biological Evaluation (ISO 10993-1)
- Cytotoxicity (ISO 10993-5)
- Maximization Sensitization (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Material-Mediated Pyrogenicity (ISO 10993-11)
- Sample Preparation (ISO 10993-12)
- Chemical Characterization (ISO 10993-18)
- Tests for Irritation (ISO 10993-23)

Electrical Safety and EMC

- IEC 60601-1 (*Applicable only to 10973HD*)
- IEC 60601-1-2 (*Applicable only to 10973HD*)
- IEC 60601-1-6 (*Applicable only to 10973HD*)
- IEC 60601-2-18 (3rd Edition)

Reprocessing (Cleaning and Sterilization)

- AAMI TIR12:2020
- ANSI/AAMI/ST8:2013/(R)2018
- ANSI/AAMI ST77:2013
- ANSI/AAMI ST79:2017
- ANSI/AAMI ST98:2022
- ANSI/AAMI/ISO 14937:2009/(R)2013
- ANSI/AAMI/ISO 17665-1:2006/(R)2013
- ASTM F3208-20
- DIN EN 285:2021
- DIN EN ISO 11138-1:2017
- DIN EN ISO 11138-3:2017
- EN 556-1:2002
- ISO 11737-1:2021
- ISO 11737-2:2019
- ISO 17664-1:2021
- ISO 17664-2:2021
- ISO 17665-2:2009
- Reprocessing Medical Device in Health Care Settings: Validation Methods and Labeling

	Comparative bench testing between the subject and predicate devices demonstrated that the <i>KARL STORZ Mediastinoscopes and Instruments</i> have met all design specifications and are substantially equivalent to the predicate devices.
Clinical Performance Data	Published literature supports the safety and effectiveness of the mediastinoscopes and associated instruments, which are intended to aid in visualization of the mediastinum and to facilitate the introduction and removal of surgical instruments during endoscopic surgical procedures in adults and pediatric patients ≥ 12 years of age and the associated instruments intended for lymph node biopsy, removal of lymphatic nodes and tumors, and for grasping and dissecting tissue for the diagnosis and treatment of pleural, parenchymal, and mediastinal disease in adults and pediatric patients ≥ 12 years of age.
Conclusion:	The conclusions drawn from the non-clinical tests demonstrate that the subject device, the <i>KARL STORZ Mediastinoscopes and Instruments</i> are as safe and effective as the predicate devices and support substantial equivalence to the predicate devices.