December 5, 2025

Karl Storz Se & Co. Kg
Trujillo Mario
Regulatory Affairs Specialist
2151 E. Grand Avenue
Dr.-Karl-Storz-Straße 34 Baden-Wurttemberg
Tuttlingen, DE 78532
Germany

Re: K251731
Trade/Device Name: KARL STORZ Flexible Intubation Video Endoscope - Sterile (FIVE-S) (0916612)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: November 7, 2025
Received: November 7, 2025

Dear Trujillo Mario:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Joyce C. Lin -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251731

Device Name
KARL STORZ Flexible Intubation Video Endoscope – Sterile (FIVE-S) (0916612)

Indications for Use *(Describe)*
The Flexible Intubation Video Endoscope – Sterile (FIVE-S) is intended for use by physicians for endotracheal intubation and diagnostic and therapeutic procedures in bronchoscopy. The Karl Storz Video Bronchoscope is intended to provide visualization via a video monitor.

E-Box: the product serves as an adaptor for operating the flexible single-use videoscope on the compatible CCU.

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.

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 and the FDA guidance document titled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" issued on July 28, 2014. All data included in this document is accurate and complete to the best of KARL STORZ SE & Co. KG knowledge.

Submitter:	KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34 78532 Tuttlingen, Germany
Contact:	Mario Trujillo Regulatory Affairs Specialist Tel.: (424) 218-8481 Email: Mario.Trujillo@karlstorz.com
Date of Preparation:	June 5, 2025
Type of 510(k) Submission:	Special
Device Identification:	Trade Name: KARL STORZ Flexible Intubation Video Endoscope – Sterile (FIVE-S) Classification Name: Bronchoscope (flexible or rigid) and accessories (21 CFR Part 876.4680);
Regulatory Class:	II
Product Code:	EOQ
Guidance Document:	Not Applicable
Predicate Device:	Predicate device: KARL STORZ Flexible Intubation Video Endoscope – Sterile (FIVE-S) (K212656).
Device Description:	The videoscopes in the modified Flexible Intubation Video Endoscope – Sterile (FIVE-S) is sterile single-use, flexible video-endoscopes. The distal tip houses the CMOS (Complementary Metal Oxide Semiconductor) imaging sensor and the LED light source. The raw data captured at the distal tip CMOS imaging censor is transferred to the E-Box adaptor (when using the Image1 S CCU), where it is converted to a standard NTSC (National Television System Committee) video signal by the PCB (Printed Circuit Board), which is then driven into the compatible CCU (Camera Control Unit) for further processing and video formatting for output to a display monitor. The videoscopes and E-Box are powered by the CCUs through the connecting cords.
Intended Use:	Intubation endoscopes are used for oral or nasal endotracheal intubation. Intubation endoscopes are designed for transient use in invasive procedures through a body orifice. Intubation endoscopes are used to inspect the upper and lower airways, to check the tube position with double lumen tubes and for monitoring during PCT.

<table>
<tr><td>Indications For Use:</td><td>The Flexible Intubation Video Endoscope – Sterile (FIVE-S) is intended for use by physicians for endotracheal intubation and diagnostic and therapeutic procedures in bronchoscopy. The Karl Storz Video Bronchoscope is intended to provide visualization via a video monitor.

E-Box: the product serves as an adaptor for operating the flexible single-use videoscope on the compatible CCU.</td></tr>
<tr><td>Technological Characteristics:</td><td>Comparison Table: Subject vs. Predicate Device
<table>
<tr><th></th><th>Subject Device

Flexible Intubation Video Endoscope – Sterile (FIVE-S)</th><th>Predicate Device, K212656

Flexible Intubation Video Endoscope – Sterile (FIVE-S)</th></tr>
<tr><td>Maximal Outer diameter Insertion Portion</td><td>6.2 mm</td><td>5.3 mm</td></tr>
<tr><td>Outer diameter Insertion Tube</td><td>6.5 mm</td><td>5.3 mm</td></tr>
<tr><td>Outer diameter Distal End</td><td>6.5 mm</td><td>5.3 mm</td></tr>
<tr><td>Insertion portion length</td><td>650 mm</td><td>650 mm</td></tr>
<tr><td>Working channel</td><td>Present</td><td>Present</td></tr>
<tr><td>Inner diameter Working Channel</td><td>3.0 mm</td><td>2.2 mm</td></tr>
<tr><td>Tip deflection up/down</td><td>180°/140°</td><td>180°/180°</td></tr>
<tr><td>Field of view</td><td>110°</td><td>110°</td></tr>
<tr><td>Direction of View</td><td>0°</td><td>0°</td></tr>
<tr><td>Depth of Field</td><td>5 – 50 mm</td><td>5 – 50 mm</td></tr>
<tr><td>On-axis Resolution</td><td>12.5 Lp/mm at 5 mm
4.5 Lp/mm at 15 mm
1.25 Lp/mm at 50 mm</td><td>12.5 Lp/mm at 5 mm
4.5 Lp/mm at 15 mm
1.25 Lp/mm at 50 mm</td></tr>
<tr><td>Chip type</td><td>CMOS</td><td>CMOS</td></tr>
<tr><td>Chip location</td><td>Distal</td><td>Distal</td></tr>
<tr><td>Illumination source</td><td>LED</td><td>LED</td></tr>
<tr><td>E-Box type</td><td>8-pin</td><td>8-pin</td></tr>
<tr><td>Compatible CCU</td><td>C-MAC
Image1 S
Tele Pack +</td><td>C-MAC
Image1 S
Tele Pack +</td></tr>
<tr><td>How device is provided</td><td>Sterile single-use</td><td>Sterile single-use</td></tr>
<tr><td>EO Sterilization cycle</td><td>EO, Overpressure 2.7 bar absolute, 8.5 % ETO in 91.5 % CO2</td><td>EO, Overpressure 2.7 bar absolute, 8.5 % ETO in 91.5 % CO2</td></tr>
<tr><td>Sterilizing Agent</td><td>Ethylene Oxide (EO)</td><td>Ethylene Oxide (EO)</td></tr>
</table></td></tr>
<tr><td>Non-Clinical Performance Data:</td><td>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:

• Electrical Safety and EMC
○ IEC 60601-1
○ IEC 60601-1-2
○ IEC 60601-2-18</td></tr>
</table>

	○ IEC 62471 ○ ISO 10993 ○ ISO 8600 Additional bench testing was performed to ensure the device met its design specifications. The bench testing performed verified and validated that the Flexible Intubation Video Endoscope – Sterile (FIVE-S) has met all its design specification and is substantially equivalent to its predicate devices.
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 Intubation Video Endoscope – Sterile (FIVE-S) performs as well as the predicate device.