December 29, 2021

KARL STORZ Endoscopy-America, Inc.
Mario Trujillo
Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, California 90245

Re: K212656
Trade/Device Name: Flexible Intubation Video Endoscope - Sterile (FIVE-S)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: November 23, 2021
Received: November 30, 2021

Dear Mario Trujillo:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212656

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

Indications for Use *(Describe)*
The Flexible Intubation Video Endoscope – Sterile (FIVE-S) are intended for use by physicians for endotracheal intubation and diagnostic and therapeutic procedures in nasal, sinus and nasopharyngeal endoscopy, bronchoscopy, tracheoscopy and esophagoscopy and laryngoscopy. 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.

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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 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 Associate Regulatory Affairs Specialist Tel.: (424) 218-8481 Email: Mario.Trujillo@karlstorz.com
Date of Preparation:	August 20, 2021
Type of 510(k) Submission:	Special
Device Identification:	Trade Name: Flexible Intubation Video Endoscope – Sterile (FIVE-S) Classification Name: Bronchoscope (flexible or rigid) and accessories (21 CFR Part 876.4680);
Regulatory Class:	2
Product Code:	EOQ
Guidance Document:	Not Applicable
Predicate Device:	Predicate device: KARL STORZ Flexible Video ENT Endoscope System (K071530). Reference devices: KARL STORZ CMOS Video Rhino-Laryngoscope SSU (K192090). KARL STORZ Flexible HD Cysto-Urethroscope System (K182723)
Device Description:	The Flexible Intubation Video Endoscope – Sterile (FIVE-S) is a 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, 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 one of the CCUs (C-MAC, C-HUB II) 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.

Indications For Use:

The Flexible Intubation Video Endoscope – Sterile (FIVE-S) are intended for use by physicians for endotracheal intubation and diagnostic and therapeutic procedures in nasal, sinus and nasopharyngeal endoscopy, bronchoscopy, tracheoscopy and esophagoscopy and laryngoscopy. 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.

Technological Characteristics:

Comparison Table: Subject vs. Predicate and Reference Devices

	Subject Device **Flexible Intubation Video Endoscope – Sterile (FIVE-S)**	**Predicate Device, K071530** **Flex. Intubation Video Endoscope**	**Reference Device:** **CMOS Video Rhino-Laryngoscope SSU (K192090)**
Maximal Outer diameter Insertion Portion	5.3 mm	5.5mm	3.5 mm
Outer diameter Insertion Tube	5.3 mm	5.5mm	3.5 mm
Outer diameter Distal End	5.3 mm	5.5mm	3.5 mm
Insertion portion length	650 mm	Same as subject device	300 mm
Working channel	Present	Same as subject device	Not Present
Inner diameter Working Channel	2.4 mm	2.2mm	No Channel
Tip deflection up/down	180°/180°	180°/100°	140°/140°
Field of view	110°	120°	Same as subject device
Direction of View	0°	Same as subject device	Same as subject device
Depth of Field	5 – 50 mm	Same as subject device	Same as subject device
On-axis Resolution	12.5 Lp/mm at 5 mm 4.5 Lp/mm at 15 mm 1.25 Lp/mm at 50 mm	No data available	Same as subject device
Chip type	CMOS	Same as subject device	Same as subject device
Chip location	Distal	Same as subject device	Same as subject device
Illumination source	LED	Same as subject device	Same as subject device
E-Box type	8-pin	N/A	6-pin
Compatible CCU	C-MAC C-HUB II	Same as subject device	Same as subject device
How device is provided	Sterile single-use	Unsterile, reusable	Same as subject device
EO Sterilization cycle	EO, Overpressure 2.7 bar absolute, 8.5 % ETO in 91.5 % CO2	N/A	Same as subject device
Sterilizing Agent	Ethylene Oxide (EO)	N/A	Same as subject 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 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 ○ IEC 62471 ○ ISO 10993 ○ ISO 8600 • Performance Testing ○ Color Contrast Enhancement ○ Image intensity uniformity ○ Depth of field & Spatial Resolution ○ Distortion ○ Signal-to-Noise Ratio (SNR) & Sensitivity 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 devices, the Flexible Intubation Video Endoscope – Sterile (FIVE-S) performs as well as the predicate device.