



September 15, 2026

Karl Storz SE & CO. KG
Jennifer Downing
Senior Regulatory Affairs Specialist
Dr.-Karl-Storz-Straße 34
Tuttlingen, BW 78532
Germany

Re: K254299

Trade/Device Name: KARL STORZ CLEARVISION Irrigation Sheath 0° (7241AS); KARL STORZ
CLEARVISION Irrigation Sheath 30° (7241BS); KARL STORZ
CLEARVISION Irrigation Sheath 45° (7241FS)

Regulation Number: 21 CFR 874.4760

Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories

Regulatory Class: Class II

Product Code: EOB

Dated: August 14, 2026

Received: August 14, 2026

Dear Jennifer Downing:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

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

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.

K254299

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Please provide the device trade name(s).

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KARL STORZ CLEARVISION Irrigation Sheath 0° (7241AS);
KARL STORZ CLEARVISION Irrigation Sheath 30° (7241BS);
KARL STORZ CLEARVISION Irrigation Sheath 45° (7241FS)

Please provide your Indications for Use below.

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The irrigation sheaths are intended to provide irrigation in endoscopic diagnosis and surgical interventions in the nasal cavity and paranasal sinuses.

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 KARL STORZ's knowledge.

Submitter:	KARL STORZ SE & CO. KG Dr.-Karl-Storz-Straße 34 Tuttlingen, Baden-Wurttemberg, Germany, 78532 Establishment Registration Number: 9610617
Contact:	Jennifer Downing Senior Regulatory Affairs Specialist jennifer.downing@karlstorz.com Tel.: 1-424-218-8115
Date of Preparation:	September 14, 2026
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Names: KARL STORZ CLEARVISION Irrigation Sheath 0° (7241AS); KARL STORZ CLEARVISION Irrigation Sheath 30° (7241BS); KARL STORZ CLEARVISION Irrigation Sheath 45° (7241FS)
Common Name:	Irrigation Sheaths
Regulatory Class:	II
Product Code:	EOB (Nasopharyngoscope, flexible or rigid)
Classification Name:	874.4760 - Nasopharyngoscope (flexible or rigid)
Device Panel:	Division of Ear Nose & Throat Devices
Predicate Device(s):	K943816, KARL STORZ Trocars, Cannulae, Sheaths The predicate device has not been subject to any recalls.
Device Description:	The subject devices are stainless steel sheaths, into which a telescope (a type of rigid endoscope) is inserted and locked in place. The subject devices have a LUER-Lock connection for irrigation. Irrigation fluid flows through the connection and out the tip of the sheath, providing irrigation to the distal tip of the telescope. The subject devices have a 4.8 mm outer diameter and a 14 cm working length.

Indications For Use:	The irrigation sheaths are intended to provide irrigation in endoscopic diagnosis and surgical interventions in the nasal cavity and paranasal sinuses.	
Environment of use	Hospital and clinic	
Technological Characteristics:	The comparison of technological characteristics is as follows:	
	Subject Device	Predicate K943816
Type of Device	Sinus irrigation Sheaths	Sinus suction / irrigation sheaths
Outer Diameter	4.8 mm	6.1 mm
Inner Diameter	4.3 mm	2.95 - 4.0 mm
Working length	14 cm	12 cm
Viewing angle / Tip Angle	0° - 45°	0° - 70°
Design of Handle	No handle	Detachable pistol grip handle with stopcock and suction / irrigation connections
Tubing connection for irrigation	LUER-Lock	LUER-Lock
Suction connection	No suction	Yes, LUER-Lock, on separate handle

Non-Clinical Performance Data:	There are no performance standards or special controls developed under Section 514 of the FD&C Act for Irrigation Sheaths. However, the subject device follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance: <u>Biocompatibility testing</u> The system complies with the following standards: • ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process • ISO 10993-2: Biological evaluation of medical devices – Part 2: Animal welfare requirements • ISO 10993-5: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity • ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests skin sensitization • ISO 10993-11: Biological evaluation of medical devices – Part 11: Tests for systemic toxicity • ISO 10993-12: Biological evaluation of medical devices – Part 12: Sample preparation and reference materials • ISO 10993-18: Biological evaluation of medical devices – Part 18: Chemical characterization of materials • ISO 10993-23 Biological evaluation of medical devices – Part 23: Tests for irritation <u>Reprocessing Validation</u> The reprocessing data submitted complies with the following standards and guidance with regards to cleaning and sterilization: • ISO 17664-1: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices • TIR12:2020: Designing testing and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers • ST79:2017: Comprehensive guide to steam sterilization and sterility assurance in health care facilities • ISO 14937: Sterilization of health care products — General requirements for characterization of a sterilizing agent and
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	the development, validation and routine control of a sterilization process for medical devices • ISO 17665-1: Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices • FDA Guidance Document Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling • ANSI / AAMI ST98: Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices • ANSI/AAMI ST77: Containment devices for reusable medical device sterilization <u>Bench Testing</u> The following bench testing was performed: • Flow Rate and Leak Test • Bending Test
Clinical Performance Data:	Clinical testing was not required to demonstrate the substantial equivalence to the predicate device. Non-clinical bench testing was sufficient to assess safety and effectiveness and to establish the substantial equivalence of the modifications.
Conclusion:	The conclusions drawn from the non-clinical tests demonstrate that the subject device, KARL STORZ Irrigation Sheaths, is as safe and effective as the predicate device and supports substantial equivalence to the predicate device.