May 11, 2026

Karl Storz SE & CO. KG
Mario Trujillo
Regulatory Affairs Specialist
Dr.-Karl-Storz-Straße 34 Baden-Wurttemberg
Tuttlingen, Delaware 78562

Re: K254228
Trade/Device Name: KARL STORZ Trocars with Valve Seals
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 26, 2025
Received: December 26, 2025

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 (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.05.11 10:25:15 -04'00'

Colin K. Chen, Ph.D.
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and
Infection Control 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.	K254228

Please provide the device trade name(s).

KARL STORZ Trocars with Valve Seals

Please provide your Indications for Use below.

KARL STORZ Trocars with Valve seals are intended to be used during endoscopic and laparoscopic procedures in general surgery and thoracoscopy in adult and pediatric patients to create and maintain a port of entry.

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)

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:	December 26, 2026
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ Trocars with Valve seals Classification Name: Laparoscope, General & Plastic Surgery (21 CFR Part 876.1500);
Regulatory Class:	II
Product Code:	GCJ
Guidance Document:	Not applicable
Predicate Devices:	KARL STORZ New Generation Trocars (K180977)
Device Description:	The KARL STORZ Trocars with Valve seals provide a port of entry during endoscopic and laparoscopic procedures in pediatric and adult patients. The KARL STORZ Trocars with Valve seals consist of a cannula, trocar, and a valve seal. The trocars combine single-use and reusable components since the valve seal is single use while the cannula and trocar are reusable components. The trocars are available with pyramidal, conical, or conical-blunt tips. Reducers can be used to reduce the size of the trocar to accommodate a smaller instrument without losing pneumoperitoneum.
Indications For Use:	KARL STORZ Trocars with Valve seals are intended to be used during endoscopic and laparoscopic procedures in general surgery and thoracoscopy in adult and pediatric patients to create and maintain a port of entry.

Substantial equivalence

Comparison Table: Subject vs. Predicate Device

	Subject Device KARL STORZ Trocars with Valve seals	Predicate Device, K180977 KARL STORZ New Generation Trocars
Indication for Use		
Indications for Use	KARL STORZ Trocars with Valve seals are intended to be used during endoscopic and laparoscopic procedures in general surgery and thoracoscopy in adult and pediatric patients to create and maintain a port of entry	KARL STORZ New Generation Trocars are intended to be used during endoscopic and laparoscopic procedures in general surgery and thoracoscopy in adult and pediatric patients to create and maintain a port of entry.
Product Code	GCJ	GCJ
Target Population	Adult and pediatric general population	Adult and pediatric general population
Physical Characteristics		
Diameter	3.3-15 mm	2.5-13.5 mm
Length	5-16 cm	5 or 10 cm
Tip Design	Pyramidal, conical, blunt	Pyramidal, conical, blunt
Method of Action	Manual Insertion	Manual Insertion
Trocar Material	Stainless Steel	Stainless Steel
Cannula Material	Stainless Steel	Stainless Steel
Trocar Housing Material	PTFE (Polytetrafluoroethylene)	PEEK (Polyether Ether Ketone)
Cleaning and Sterilization Methods		
Reusable Components	Trocar, Cannula, Reducer	Trocar, Cannula, Valve, Reducer
Cleaning	Manual	Manual
Sterilization	Steam	Steam, EtO
Sterile Single-Use Components	None	Valve Seals

Non-Clinical Performance Data:

Bench verification performance testing has been performed for the following parameters:

- Seal Leak Test
- Seal Leak Test while Under Torque
- Instrument Insertion and Retention Test
- Penetration Force

Biocompatibility evaluation was performed to:

- ISO 10993

Sterility of the Reusable Components was validated in accordance with:

- ISO 11135

Clinical Performance Data:

Clinical testing was not required to demonstrate the substantial equivalence to the predicate device. Non-clinical bench testing was sufficient to establish the substantial equivalence of the modifications.

Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the subject device, KARL STORZ Trocars with Valve seals, performs as well as or better than the legally marketed predicate device.