September 22, 2025

Karl Storz SE & Co. KG
Emily Rhiel
Regulatory Affairs Specialist
Dr. Karl-Storz-Straße 34
Tuttlingen, BW 78532
GERMANY

Re: K250388
Trade/Device Name: Endoflator +
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, OSV
Dated: August 22, 2025
Received: August 22, 2025

Dear Emily Rhiel:

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,

Reginald K. Avery -S

for Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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)*
K250388

Device Name
ENDOFLATOR +

Indications for Use *(Describe)*
The ENDOFLATOR + is a CO2 insufflator intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with CO2 gas with the following operating modes:
• High Flow and Pediatric modes are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure.
• Pediatric mode is indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure in pediatrics aged 2 and up.
• EVH mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery.
• taTME mode is indicated to fill and distend the rectum and colon using CO2 gas during transanal minimally invasive surgery.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Office of Chief Information Officer
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary is being submitted in accordance with 21 CFR 807.92.

Submitter Information:	KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34 78532 Tuttlingen, Germany
	Contact: Emily Rhiel Regulatory Affairs Senior Specialist Phone: (774) 318-2820 Email: emily.rhiel@karlstorz.com
	Date of Preparation: September 22, 2025
Device Information:	Trade/Proprietary Name: ENDOFLATOR + Common Name: Laparoscopic Insufflator Classification Name: Laparoscopic Insufflator Classification Number: 21 CFR 884.1730 Product Code: HIF (primary), OSV (secondary) Regulatory Class: Class II
Predicate Device(s):	K201361 W.O.M. World of Medicine GmbH PNEUMOCLEAR The predicate device has not been subject to a design related recall.
Device Description:	The ENDOFLATOR + is an insufflation device with integrated smoke evacuation for laparoscopic examinations and surgery as well as transanal endoscopy and endoscopic vessel harvesting. Insufflation creates and maintains a cavity in the patient's body. The subject device offers four operating modes: High Flow, Pediatric, EVH, and taTME. Smoke evacuation can be used with different flow rates for removal and filtration of CO_2 and surgical smoke during operation. The ENDOFLATOR + is operated directly on the touchscreen. All data required during the surgery is displayed simultaneously on the touchscreen. The subject device is to be used with one of the following tube sets depending on the selected mode and desired features (smoke evacuation, heating, and humidification) needed: UI610 (standard), UI611 (heating), UI612 (smoke evacuation), UI613 (heating + smoke evacuation), and UI614 (heating + smoke evacuation + humidification). The tube sets are designed with a radio frequency identification (RFID) transponder technology tube set recognition function, that recognizes the type of tube set that has been connected and which functions are available based on the selection.

<table>
<tr><td>Indications for Use:</td><td>The ENDOFLATOR + is a CO_2 insufflator intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with CO_2 gas with the following operating modes:
High Flow and Pediatric modes are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure.
Pediatric mode is indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure in pediatrics aged 2 and up.
EVH mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery.
taTME mode is indicated to fill and distend the rectum and colon using CO_2 gas during transanal minimally invasive surgery.</td></tr>
<tr><td>Comparison of the Technological Characteristics:</td><td>
<table>
<tr><th></th><th>Subject Device: K250388
KARL STORZ ENDOFLATOR +</th><th>Predicate Device: K201361
W.O.M. World of Medicine
PNEUMOCLEAR</th></tr>
<tr><td>Target Population</td><td>Adults, Children, Adolescents</td><td>Adults and Pediatrics (including all pediatric sub-population)</td></tr>
<tr><td>Indications for Use</td><td>The ENDOFLATOR + is a CO2 insufflator intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with CO2 gas with the following operating modes:

• High Flow and Pediatric modes are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure.

• Pediatric mode is indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure in pediatrics aged 2 and up.

• EVH mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the</td><td>The device PNEUMOCLEAR is a CO2 insufflator intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with CO2 gas. The Standard, High Flow/Bariatric, Pediatric and Advanced Flow operating modes of the device are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure. The Pediatric operating mode is indicated for pediatric laparoscopic procedures. The Vessel Harvesting operating mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery. The TAMIS operating mode is indicated to fill and distend the rectum and colon using CO2 gas</td></tr>
</table>
</td></tr>
</table>

		saphenous vein or radial artery. • taTME mode is indicated to fill and distend the rectum and colon using CO2 gas during transanal minimally invasive surgery.	during transanal minimally invasive surgery.
	User Interface	Touchscreen	Same as subject
	Dimensions and Weight	370 x 150 x 305mm 10.7kg	318 x 149 x 429 mm 10kg
	Design	High/low pressure units Safety valve assembly Gas heater Control hardware Smoke evacuation unit	Same as subject
	User Modes	• Pediatric • High Flow • Endoscopic Vessel Harvesting (EVH) • Transanal Total Mesorectal Excision (taTME)	• Pediatric • Standard High Flow/Bariatric • Advanced Flow • Endoscopic Vessel Harvesting (EVH) • Transanal Minimally Invasive Surgery (TAMIS)
	Maximum specifications	Pressure: 30mmHg Insufflation Gas Flow: 50 L/min Smoke Evacuation Flow: 12 L/min	Same as subject
	Heating Option	Yes	Yes
	Humidification Option	Yes	Yes
	Smoke Evacuation Option	Yes	Yes
	Insufflation Tubing Sets	• Standard (UI610) • Heating (UI611) • Smoke Evacuation (UI612) • Heating + Smoke Evacuation (UI613)	• Model ST295: Insufflation tube set with integrated filter • Model ST296: Insufflation tube set with integrated filter and heating wire • Model ST297: Insufflation tube set with

		• Heating + Smoke Evaluation + Humidification (UI614)	integrated filter, heating wire and humidification • Model ST298: Insufflation and smoke evacuation tube set with integrated filter, heating wire and humidification • Model ST299: Insufflation and smoke evacuation tube set with integrated filter

The subject device has the same intended use. The differences, including available tubing sets and user modes, between the subject device and predicate device do not raise different questions of safety and effectiveness and their acceptability have been confirmed through performance testing.

Non-Clinical Performance Data:

The following non-clinical performance data were provided in support of the substantial equivalence determination.

<u>Sterilization Validation</u>

The insufflation tubing sets are sterilized with ethylene oxide (EO) and the sterilization of the tube sets was validated per ISO 11135 (2018). Using the overkill approach, the EO limit was validated per ISO 10993-7 (2019).

<u>Packaging Integrity/simulated Shipping Distribution Validation</u>

Transport validation of the devices is provided. The methods used in testing comply with the following standards:

- ASTM D4169 (2016): Standard practice for performance testing of shipping containers and systems
- ASTM D4332 (2022): Standard practice for conditioning containers packages or packaging components for testing
- ASTM F2096 (2011): Standard test method for detecting gross leaks in packaging by internal pressurization (bubble test)
- ASTM F1929 (2015): Standard test method for detecting seal leaks in porous medical packaging by dye penetration
- ASTM F88 (2015): Standard test method for seal strength of flexible barrier materials
- ASTM D5276 (2019): Standard Test Method for Drop Test of Loaded Containers by Free Fall
- ASTM D999-08 (2015): Standard Test Method for Vibration Testing of Shipping Containers

- ASTM D4728 (2017): Standard Test Method for Random Vibration Testing of Shipping Containers
- ASTM D6344 (2017): Standard Test Method for Concentrated Impacts to Transport Packages

Shelf-Life Validation

Accelerated aging test reports to support 3 years of shelf life are submitted, which demonstrate that device packaging and efficacy are retained. Packaging tests methods comply with the standards listed above for packaging validation. Testing consisted of visual inspection of package (ASTM F1886/F1886M (2016)), dye penetration (ASTM F1929 (2015)), and seal strength test (ASTM F88/F88M (2015)), in addition to microbial barrier properties (agar contact challenge test /DIN 58953-6) and burst test (ASTM F1 140/F1 140M (2013)) which were conducted after accelerated aging (ASTM F 1980 (2021)).

Software and Cybersecurity Validation

- Software verification and validation testing were conducted and documentation was provided as recommended by the FDA's guidance, "*Content of Premarket Submissions for Device Software Functions.*" The document level is Enhanced.
- The cybersecurity was evaluated according to the FDA guidance "Cybersecurity in Medical Device: Quality System Considerations and Content of Premarket Submissions"

Electrical Safety & EMC Evaluation

Electrical Safety & EMC testing was conducted in compliance with the following standards:

- IEC 60601-1 (2020): Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6 (2020): Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-18 (2009): Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

Bench Testing

	Verification testing of all user-modes and functions are provided including: • High Flow mode • Pediatrics mode • EVH mode • taTME mode • Heating and Humidification functions • Smoke Evacuation function • Overpressure Detection, Occlusion, and Gas Consumption • Tubing Set Compatibility and RFID • Desufflation
Conclusion:	The conclusions drawn from the non-clinical performance data demonstrate that the subject device is as safe and effective as the predicate device. As such, the subject device is substantially equivalent to the predicate device.