August 19, 2026

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

Re: K260209
Trade/Device Name: ENDOFLATOR+; Smart Smoke Evacuation
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, OSV
Dated: July 30, 2026
Received: July 30, 2026

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 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,

JASON ROBERTS -S

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

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.	K260209

Please provide the device trade name(s).

ENDOFLATOR+;
Smart Smoke Evacuation

Please provide your Indications for Use below.

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 mode is 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 pediatric laparoscopic procedure.
• 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.

The smart smoke evacuation software is an optional feature that triggers smoke evacuation of the compatible insufflator through analysis of the smoke volume in the endoscopic image.

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.

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: August 17, 2026
Device Information:	Trade/Proprietary Name: ENDOFLATOR +; Smart Smoke Evacuation 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):	**Insufflator predicates:** K250388 KARL STORZ ENDOFLATOR + K201361 W.O.M. World of Medicine GmbH PNEUMOCLEAR **Smart Smoke predicate:** K201434 Stryker Connected OR Hub with Voice and Device Control The predicate devices have 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. When used as a standalone insufflator, smoke evacuation can be used in HF, Continuous, or Manual Activation mode. When the insufflator is combined with the IMAGE1 CCU, Smart mode becomes available which enables the insufflator to conduct automatic smoke evacuation through analysis of the endoscopic image. The ENDOFLATOR + is operated directly on the touchscreen. All data required during the surgery is displayed simultaneously on the

	touchscreen. The data can also be routed to display the primary surgical monitor when the insufflator is network enabled. 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.
Indications for Use:	<u>ENDOFLATOR +</u> 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 mode is 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 pediatric laparoscopic procedure. • 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. <u>Smart Smoke Evaucation</u> The smart smoke evacuation software is an optional feature that triggers smoke evacuation of the compatible insufflator through analysis of the smoke volume in the endoscopic image. <u>Comparison to Predicates</u> The subject device's pediatric mode is expanded to include patients under 2 years old, which was excluded from the initial clearance (K250388). However, this patient population is included in the indications of the K201361 predicate. The smart smoke evacuation software indications differ from the K201434 predicate, as the subject device only accomplishes automatic smoke detection and evacuation, while the Stryker Connected OR

<table>
<tr><td></td><td>system also includes voice and remote control of medical devices in addition to automatic smoke evacuation.
Considering the indications of all three predicates together, the indications of the subject device, Endoflator + with Smart Smoke Evacuation, do not introduce any new indications.</td></tr>
<tr><td>Comparison of the Technological Characteristics:</td><td>
<table>
<tr><th colspan="4">Insufflator Comparison</th></tr>
<tr><th></th><th>Subject Device:
KARL STORZ ENDOFLATOR + with Smart Smoke Evacuation</th><th>Predicate Device:
K250388
KARL STORZ ENDOFLATOR +</th><th>Predicate Device:
K201361
W.O.M PNEUMOCLEAR</th></tr>
<tr><td>Target Population</td><td>Adults and Pediatrics (all sub-populations)</td><td>Adults, Children, Adolescents</td><td>Same as subject</td></tr>
<tr><td>User Interface</td><td>Touchscreen</td><td>Same as subject</td><td>Same as subject</td></tr>
<tr><td>Dimensions and Weight</td><td>370 x 150 x 305mm
10.7kg</td><td>Same as subject</td><td>Same as subject</td></tr>
<tr><td>Design</td><td>High/low pressure units
Safety valve assembly
Gas heater
Control hardware
Smoke evacuation unit</td><td>Same as subject</td><td>Same as subject</td></tr>
<tr><td>User Modes</td><td>• Pediatric:
○ <2 years
○ ≥2 years
• High Flow
• Endoscopic Vessel Harvesting (EVH)
• Transanal Total Mesorectal Excision (taTME)</td><td>• Pediatric ≥2 years
• High Flow
• Endoscopic Vessel Harvesting (EVH)
• Transanal Total Mesorectal Excision (taTME)</td><td>• Pediatric
• Standard High Flow/Bariatric
• Advanced Flow
• Endoscopic Vessel Harvesting (EVH)
• Transanal Minimally Invasive Surgery (TAMIS)</td></tr>
<tr><td>Maximum specifications</td><td>Pressure: 30mmHg
Insufflation Gas Flow: 50 L/min</td><td>Same as subject</td><td>Same as subject</td></tr>
</table>
</td></tr>
</table>

	Smoke Evacuation Flow: 12 L/min		
Tubing Set Features	Heating Humidification Smoke Evacuation	Same as subject	Same as subject
Smoke Evacuation Modes	HF Continuous Smart Manual Activation	HF Continuous Manual Activation	Information not available
Insufflation Tubing Sets	Standard (UI610) Heating (UI611) Smoke Evacuation (UI612) Heating + Smoke Evacuation (UI613) Heating + Smoke Evaluation + Humidification (UI614)	Same as subject	Insufflation tube set with integrated filter (ST295) Insufflation tube set with integrated filter and heating wire (ST296) Insufflation tube set with integrated filter, heating wire and humidification (ST297) Insufflation and smoke evacuation tube set with integrated filter, heating wire and humidification (ST298) Insufflation and smoke evacuation tube set with integrated filter (ST299)

Smart Smoke Evacuation Comparison		
	Subject Device: KARL STORZ ENDOFLATOR + with Smart Smoke Evacuation	**Predicate Device: K201434** Stryker Connected OR Hub with Device and Voice Control
System Components	ENDOFLATOR + and insufflation tubing IMAGE1 CCU with Smart Smoke Evacuation Software	PNEUMOCLEAR and insufflation tubing Connected OR Hub console Device control and voice control software
Smoke Detection	Automated	Same as subject
Smoke Evacuation	Automated	Same as subject

	<table><tr><td>**Digital Smoke Removal**</td><td>No</td><td>Yes</td></tr></table> The subject device has the same intended use as the predicates. The differences between the subject device and predicates do not raise different questions of safety and effectiveness and have been confirmed through testing.
Non-Clinical Performance Data:	The following non-clinical performance data were provided in support of the substantial equivalence determination. <u>Software and Cybersecurity Validation</u> • Software verification and validation testing was conducted and documentation was provided as recommended by the FDA's guidance, "*Content of Premarket Submissions for Device Software Functions.*" • The cybersecurity was evaluated according to the FDA guidance "*Cybersecurity in Medical Device: Quality System Considerations and Content of Premarket Submissions.*" <u>Bench Testing</u> • Pediatric Mode: Testing of the subject device's pediatric mode compared to the K201361 PNEUOMOCLEAR device was conducted to verify that the subject device's mode was as safe & effective as the predicate for pediatrics under 2 years old. • Smart Smoke: Verification testing to demonstrate correct identification of smoke level and smoke evacuation trigger was conducted. Additionally, rapid activation/deactivation of smoke evacuation was simulated to demonstrate that smart smoke does not increase the risk of over or under pressure during use. All bench testing passed, thus demonstrating that the expansion of the pediatric patient population and smart smoke evacuation are safe & effective to use as indicated.
Conclusion:	The conclusions drawn from the non-clinical performance data demonstrate that the subject device is as safe and effective as the predicate devices. As such, the subject device is substantially equivalent to the predicate devices.