July 16, 2026

Karl Storz Se & Co. Kg
Emily Rhiel
Senior Regulatory Affairs Specialist
Dr.-Karl-Storz-Strabe 34
Tuttlingen, Baden-Wurttemberg 78532
GERMANY

Re: K261706
Trade/Device Name: Endomat Select (UP220)
Regulation Number: 21 CFR 884.1700
Regulation Name: Hysteroscopic Insufflator
Regulatory Class: II
Product Code: HIG, LJH, BTA, EOB, HRX, OCX
Dated: May 22, 2026
Received: May 22, 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: The Center for Devices an Radiological Health (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, the Food and Drug Administration (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.	K261706

Please provide the device trade name(s).

Endomat Select (UP220)

Please provide your Indications for Use below.

Endomat Select is intended to:.
• provide the infusion of the sterile irrigation solution into the ureter and upper urinary tract, as well as to suction irrigation fluids, bodily fluids, secretions, tissue and gas during diagnostic and operative endoscopic urological procedures.
• provide the infusion of the sterile irrigation solution into the uterus, as well as to suction irrigation fluids, bodily fluids, secretions, tissue and gas during diagnostic and operative endoscopic hysteroscopic procedure.
• provide the infusion of the sterile irrigation solution into organs and operating fields during diagnostic and operative endoscopic procedures in laparoscopic and open general surgery.
• provide sustained liquid irrigation and distention of joint or intra-articular spaces as well as to suction irrigation fluids, bodily fluids, secretions, tissue and gas during all phases of arthroscopic surgery.
• provide the infusion of the sterile irrigation solution in order to enable cleaning of the lens during endoscopically assisted Functional Endoscopic Sinus Surgery.

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)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☐ Adults (22 years old and greater)

510(k) Summary

Submitter:	KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34 78532 Tuttlingen, Germany
Contact:	Emily Rhiel Senior Regulatory Affairs Specialist Tel.: (774) 318-2820 Email: Emily.Rhiel@karlstorz.com
Date of Preparation:	July 16, 2026
Type of 510(k) Submission:	Traditional 510(k)
Device Identification:	Trade Name: Endomat Select (UP220) Common Name: Hysteroscopic Insufflator Regulation Number: 21 CFR 884.1700
Regulatory Class:	II
Product Code:	HIG, BTA, LJH, HRX, OCX, EOB
Guidance Document:	Hysteroscopic and Laparoscopic Insufflators: Submission Guidance for a 510(K) issued on August 1, 1995 for Product Code HIG
Predicate Devices:	KARL STORZ Endomat Select (K201355) The predicate has not been subject to a design related recall.
Device Description:	The Endomat Select is a multi-functional, pressure-controlled, combined irrigation and suction pump. It can be used for irrigation and, where appropriate dilation, during Hysteroscopic (HYS), Arthroscopic (ART), Urological (URO) and General Surgical or Laparoscopic (SURG) interventions. The device can be used for suction during Urological (URO) and Hysteroscopic (IBS) interventions. In addition, the device can function in an oscillatory mode (ENT) providing a fluid means to maintain lens clarity during use in Transnasal procedures. The device has a modern LCD display with touch screen user interface. The tubing sets are encoded so that they can be identified by the device, which selects the appropriate operating modes based on the tubing set connected. The device also has network connectivity which can be used for remote servicing and to connect to other KARL STORZ devices proprietary network communication protocol (HIVE).
Indications For Use:	Endomat Select is intended to:. • provide the infusion of the sterile irrigation solution into the ureter and upper urinary tract, as well as to suction irrigation fluids, bodily fluids, secretions, tissue and gas during diagnostic and operative endoscopic urological procedures.

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<tr><td></td><td>

- provide the infusion of the sterile irrigation solution into the uterus, as well as to suction irrigation fluids, bodily fluids, secretions, tissue and gas during diagnostic and operative endoscopic hysteroscopic procedure.
- provide the infusion of the sterile irrigation solution into organs and operating fields during diagnostic and operative endoscopic procedures in laparoscopic and open general surgery.
- provide sustained liquid irrigation and distention of joint or intra-articular spaces as well as to suction irrigation fluids, bodily fluids, secretions, tissue and gas during all phases of arthroscopic surgery.
- provide the infusion of the sterile irrigation solution in order to enable cleaning of the lens during endoscopically assisted Functional Endoscopic Sinus Surgery.

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<tr><td>Predicate Indications for Use</td><td>Endomat Select is intended to:

- provide the infusion of the sterile irrigant solutions into the ureter and upper urinary tract, as well as to suction off the irrigation fluids, bodily fluids, secretions, tissue and gas during diagnostic and operative endoscopic urological procedures
- provide the infusion of the sterile irrigant solutions into the uterus, as well as to suction off the irrigation fluids, bodily fluids, secretions, tissue and gas during diagnostic and operative endoscopic hysteroscopic procedures
- provide the infusion of the sterile irrigant solutions into organs and operating fields during diagnostic and operative procedures in laparoscopic and open general surgery
- provide sustained liquid irrigation and distention of joint or intra-articular spaces during all phases of arthroscopic surgery
- provide the infusion of the sterile irrigant solutions in order to enable the Lens Cleaning during endoscopically assisted Functional Endoscopic Sinus Surgery and endoscopically assisted transnasal pituitary gland surgery</td></tr>
<tr><td>Indications for Use Comparison</td><td>The subject device extends the arthroscopy indication to include suction, in addition to the cleared arthroscopic irrigation indications. The subject device also removes the indications for use during “endoscopically assisted Transnasal Pituitary Gland Surgery”. The modifications to not introduce a new intended use.</td></tr>
<tr><td>Technological Characteristics:</td><td>
<table>
<tr><th></th><th>Subject device</th><th>Predicate Device
K201355</th></tr>
<tr><td>Intended Use</td><td>Suction/irrigation pumps and their accessories are used for the introduction of irrigation fluids into organs, joints and operating fields as well as the suctioning off of irrigation fluids and bodily fluids, secretions, tissue and gas during diagnostic or therapeutic interventions.</td><td>Same as subject</td></tr>
<tr><td>Device Design</td><td>Microprocessor controlled, pressure monitoring peristaltic pump for irrigation and flow controlled peristaltic pump for suction</td><td>Same as subject</td></tr>
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</table>

Device Type	Roller-pump	Same as Subject
Input/Output devices	LED touch screen	Same as subject
Maximum Suction pressure	-0.96 bar	Same as subject
Maximum Irrigation pressure	500 mmHg	Same as subject
Irrigation Pressure	Gen/Lap surgery: 100, 300 and 500 mmHg Hyst: 20-150 mmHg Uro: 20-150 mmHg Uro (irrigation RES): 20 – 150 mmHg Arth:20-150 mmHg ENT: N/A	Gen/Lap surgery: 100, 300 and 500 mmHg Hyst: 20-150 mmHg Uro: 20-150 mmHg Arth:20-150 mmHg ENT/**Neuro**: N/A
Irrigation Flow	Gen/Lap Surgery: 100-3500 ml/min Hyst: 200, 400, 600 ml/min Uro: 200, 400, 600 ml/min **Uro (irrigation RES): 200, 400, 600 ml/min** Arth: 1500, 2000, 2500 ml/min ENT: 50, 65, 80, 95, 110, 130 ml/min	Gen/Lap Surgery: 100-3500 ml/min Hyst: 200, 400, 600 ml/min Uro: 200, 400, 600 ml/min Arth: 1500, 2000, 2500 ml/min ENT/**Neuro**: 50, 65, 80, 95, 110, 130 ml/min
Suction Pressure	Hyst (suction): N/A IBS (suction): N/A Uro (suction RES): N/A **Arth (suction): N/A**	Hyst: N/A IBS (suction): N/A Uro (suction RES): N/A **Uro (Calcuson): N/A**
Suction Flow	**Hyst (suction): 10 – 180 ml/min** IBS (suction): 100 – 300 ml/min Uro (suction RES): 100 – 1000 ml/min **Arth (suction): 100 – 1000 ml/min**	Hyst (suction): N/A IBS (suction): 100 – 300 ml/min Uro (suction RES): 100 – 1000 ml/min **Uro (Calcuson): 300 – 1000 ml/min**
Service/update function	Remote or on-site	On-site
Software Packages	UP601 – SURGERY; includes procedures "LAP", "THOR" and "PROCTO" UP602 – HYSTEROSCOPY, includes procedures "HYS" (**suction** and irrigation)	UP601 – Same as subject UP602 – HYSTEROSCOPY Software, license, allows selection of the procedure "HYS" **(irrigation only)**

		UP603 – GYN Shaver, includes procedure "GYN Shaver'' (suction and irrigation) UP604 - UROLOGY, includes procedures "CYST', "PCN", "URS" and **"RES (suction and Irrigation)** UP605 – ARTHROSCOPY, includes procedures "KNEE", "HIP", "SHOULDER" and "SMALL JOINTS" **(suction and irrigation)** UP606 – ENT includes procedure "CLEARVISION" UP610 – ADVANCED BOOST Available with UP604 and UP605 irrigation modes	UP603 – Same as subject UP604 – UROLOGY, includes procedures "CYST', "PCN", "URS", "**CALCUSON**" and **"RES (suction only)** UP605 – ARTHROSCOPY, includes procedures "KNEE", "HIP", "SHOULDER" and "SMALL JOINTS**" (irrigation only)** UP606 – ENT/**NEURO**, includes procedures "CLEARVISION" UP610 – same as subject BOOST available for UP604 and UP605 irrigation mode
	The subject device has the same intended use as the predicate. The differences between the subject device and predicate device include new modes (Uro irrigation RES, Hys suction, Arth suction), remote servicing options, removal of Calcuson option for urological suction, and removal of NEURO as a procedure type for software package UP606. These differences do not raise different questions of safety and effectiveness and have been confirmed through testing.		
Non-Clinical Performance Data:	The Endomat Select follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidances: ❖ Electrical Safety and EMC ➢ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 ➢ IEC 60601-1-6:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 ➢ IEC 60601-1-8: 2006, AMD1:2012, AMD2:2020 ➢ IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020 ➢ IEC 60601-2-2: 2017 ➢ "Electromagnetic Compatibility (EMC) of Medical Devices" (June 2022) ❖ Software and Cybersecurity Verification and 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" issued in June 2023. ➢ Cybersecurity was evaluated according to the FDA guidance "Cybersecurity in Medical Device: Quality System Considerations and Content of Premarket Submissions" issued in February 20263 ➢ IEC 62304 Edition 1.1 2015-06 ❖ Stability and Shelf Life ➢ ASTM F88/F88M-23 ➢ ASTM F2096-11 ➢ ASTM F1929-23		

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- ASTM D4169-22

Bench testing was performed to ensure the device met its design specifications for the additional procedures not applicable to the predicate:

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<tr><th>Verification Test</th><th>Conclusion</th></tr>
<tr><td>HYS Suction</td><td>Pass</td></tr>
<tr><td>Flow URO RES</td><td>Pass</td></tr>
<tr><td>ART Suction</td><td>Pass</td></tr>
<tr><td>BOOST feature for URO RES</td><td>Pass</td></tr>
</table>

The bench testing verified and validated that the Endomat Select has met all its design specifications and is substantially equivalent to the predicate device.
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<tr><td>Clinical Performance Data:</td><td>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.</td></tr>
<tr><td>Conclusion:</td><td>The conclusions drawn from the nonclinical tests demonstrate that the subject device, the Endomat Select (UP220) is as safe and effective as the predicate device (UP210), which is legally marketed for the same intended use. The data support the conclusion that the subject device is substantially equivalent to the predicate device.</td></tr>
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