July 22, 2020

Karl Storz SE & Co. KG
Alexey Davidov
Manager Regulatory Affairs, US Submissions
Dr.-Karl-Storz-Strasse 34
Tuttlingen, Baden-Wurttemberg 78532
Germany

Re: K201355
Trade/Device Name: Endomat Select
Regulation Number: 21 CFR§ 884.1700
Regulation Name: Hysteroscopic insufflator
Regulatory Class: II
Product Code: HIG, BTA, GWG, HRX, LJH, OCX, EOB
Dated: June 17, 2020
Received: June 22, 2020

Dear Alexey Davidov:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 R. Roberts, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201355

Device Name

Endomat Select

Indications for Use *(Describe)*

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

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.

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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 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.

Applicant:	KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34 78532 Tuttlingen, Germany
Contact:	Alexey Davidov Manager Regulatory Affairs, US Submissions Phone: +49 (0)7461 708-7909 Fax: +49 (0)7461 708-75095 Email: Alexey.Davidov@karlstorz.com
Date of Preparation:	July 21, 2020
Type of 510(k) Submission:	Special
Device Identification:	Trade Name: Endomat Select Common Name: Suction Irrigation Pump Classification Name: Hysteroscopic insufflator (21 CFR Part 884.1700)
Class:	II
Product Codes:	Primary: HIG Secondary: BTA, GWG, HRX, LJH, OCX, EOB
Regulation:	884.1700 - Hysteroscopic insufflator
Predicate Device:	Primary predicate device: KARL STORZ Endomat Select (K180735). Secondary predicate device: KARL STORZ HAMOU Endomat (K936231). Predicates have not been subjects of design-related recalls. No reference devices were used in this submission.

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/Neuro) 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 can also be connected to other Karl Storz devices using the proprietary Storz Control Bus (SCB) [K994348]. The device protects the patient from overpressure via software means. The software-controlled pressure measurement system can stop the actuator (roller pump) should the pressure rise beyond the pre-determined limit and will immediately reverse the pump roller direction to depressurize the fluid system if required. Additionally, the device has high pressure alarms to alert the operating room staff of a high-pressure situation. The device also requires positive action from the user to increase pressures above 100mmHg; the user is prompted to confirm their choice on the user interface. The accessories for this device are provided separately. All of the accessories for use with this device are already marketed in the U.S. and are either Class I, Class II 510(k) exempt or Class II previously cleared devices. The generic tubing sets for use with this device are single use, sterile Class I accessories.

Accessory description	Part number	Marketing Status
Suction bottle, 5l, sterilizable	20300050	Class II, Exempt
Cap for suction bottle 20300050, 5l sterilizable	20300034	Class II, Exempt
Metal filter	20300038	Class II, Exempt
Bottle stand for suction bottle, 5l	20300032	Class II, Exempt
Bottle stand holder	20300033	Class II, Exempt
Suction bottle, 0,5l, sterilizable	20300051	Class II, Exempt
Cap, for suction bottle	20300039	Class II, Exempt
Bottle stand, for suction bottle	20300231	Class II, Exempt
Control cable	20701070	Class II, K973251
Single pedal footswitch	20014130	Class II, K072410
SCB connecting cord, length 100cm	20090170	Class II, K994348
Tubing Set, Irrigation, PC, for single use, sterile, package of 10	031523-10	Class I, Exempt
Tubing Set, Suction, BS, for single use, sterile, package of 10	031647-10	Class I, Exempt
Tubing Set, Suction, DS, for single use, sterile, package of 10	030647-10	Class I, Exempt
Tubing Set, Irrigation, FC, for single use, sterile, package of 10	031524-10	Class I, Exempt
Tubing Set, Irrigation, CV, for single use, sterile, package of 10	031529-10	Class I, Exempt

Intended Use:	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.
Indications for Use:	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

Indications for Use – Comparison to Predicate Devices	Primary Predicate Device (K180735) 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 liquid distension of the uterus for diagnostic and operative hysteroscopy -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 distension of the 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 Secondary Predicate Device (K936231) The Karl Storz HAMOU Endomat is a dual purpose pump system for the controlled infusion and aspiration of sterile solutions into body cavities, under control of the physician, for laparoscopic and hysteroscopic procedures. In the laparoscopic mode the suction/irrigation pump is used to infuse and aspirate sterile irrigation solution into the peritoneal cavity for rinsing or removing carbon deposits, blood clots, or excised tissue during laparoscopic and pelviscopic procedures. In the hysteroscopic mode the suction/ irrigation pump is used to infuse and aspirate sterile irrigation solution into the uterine cavity for rinsing or removing carbon deposits, blood clots, or excised tissue and provides a continuous flow of sterile liquid for the distention of the uterus during diagnostic and operative hysteroscopy. Comparison The subject device expands the indications of use of the primary predicate device to include suctioning off the irrigation fluids, bodily fluids, secretions, tissue and gas during diagnostic and operative endoscopic hysteroscopic procedures. This expanded indication for use is similar to that of the secondary predicate device; however, the secondary predicate device does not have indications for the other surgical areas (i.e. urological, general surgery, arthroscopic, etc.) listed under the subject device. The subject device does not represent a new intended use as compared to the primary and secondary predicate devices.

Technological Characteristics:

Comparison Table: Subject vs. Predicate Devices

	Subject Device	Primary Predicate Device K180785	Secondary Predicate Device K936231
	Endomat Select UP210		HAMOU Endomat
Device Design	Microprocessor controlled, pressure monitoring peristaltic pump for irrigation and flow controlled peristaltic pump for suction		Microprocessor controlled, pressure monitoring peristaltic pump for irrigation, pressure monitoring vacuum pump for suction
Device Type	Roller-pump		Suction: Vacuum-pump
Operating Modes (Irrigation)	General and Laparoscopic Surgery, Hysteroscopy, Urology, Arthroscopy, Lens Cleaning		Laparoscopy Hysteroscopy
Operating Modes (Suction)	Hysteroscopy Urology	Urology	Laparoscopy Hysteroscopy
Input/Output Devices	LED touch screen		LED light bars with foil keyboard
Suction Flow Rate	Hyst: 100-300 ml/min Uro: 100-1000 ml/min (RES mode) 300-1000 ml/min (Calcusion mode)		n/a
Suction Pressure	Hyst: max. -0.75 bar (-562.5 mmHg) Uro: max. -0.95 bar (-712.5 mmHg)	Uro: max. -0.95 bar (-712.5 mmHg)	Lap: max. -0.8 bar (-600 mmHg) Hyst: max. -0.5 bar (-375 mmHg)

The subject device features a hysteroscopy suction mode that is not present in the primary predicate device; however, it is similar to a technological feature of the secondary predicate device. Otherwise, the subject device and primary predicate device are identical.

The differences in technological characteristics do not raise different questions of safety and effectiveness.

Non-Clinical Performance Data:

As part of demonstrating substantial equivalence to the predicate, a risk analysis was completed to identify the risks associated with the Endomat Select IBS operating mode. Verification testing was conducted to evaluate the modification. The following tests associated with the device modifications were performed on the subject device according to methods and acceptance criteria outlined in the predicate device (K180735).

Verification Test	Conclusion
Operating Mode Activation	Pass
Operating Mode/Software Installation	Pass
Performance – Flow Rate	Pass
Performance – Pressure	Pass
Accessory Compatibility	Pass
Safety – Error Detection	Pass
Safety – Usability	Pass

The bench testing performed verified and validated that the Endomat Select has met all its design specifications.

Clinical Performance Data:

Clinical testing was not required to demonstrate the substantial equivalence to the predicate devices.

Conclusion:	The Endomat Select is substantially equivalent to its predicate devices. The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe and effective as the predicate devices.