October 31, 2018

Karl Storz SE & Co. KG
Nina Dusper
Regulatory Affairs Manager
Dr.-Karl-Storz-StraBe 34
Tuttlingen, 78532
Germany

Re: K180735
Trade/Device Name: Endomat Select (Model Number: UP210)
Regulation Number: 21 CFR§ 884.1700
Regulation Name: Hysteroscopic Insufflator
Regulatory Class: II
Product Code: HIG, BTA, LJH, OCX, HRX, GWG, EOB
Dated: July 30, 2018
Received: August 2, 2018

Dear Nina Dusper:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sharon M. Andrews -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K180735

Device Name
Endomat Select (Model Number: UP210)

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 irrigations fluids, bodily fluids, secretions, tissue and gas during diagnostic and operative endoscopic urological procedures

• provide liquid distention 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 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.

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

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KARL STORZ`s knowledge.

Applicant:	KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34 78532 Tuttlingen Baden-Württemberg, GERMANY
Contact:	Nina Dusper Regulatory Affairs Manager +49 (0) 7461 708-8399 +49 (0) 7461 708-105
Date of Preparation:	1st February 2018
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: Endomat Select (Model Number: UP210) Common Name: Suction Irrigation Pump
Regulation:	21 CFR 884.1700 (Hysteroscopic Insufflator)
Class:	II
Product Code:	HIG: Hysteroscopic Insufflator
Additional Product Codes:	BTA: Pump, Portable, Aspiration (Manual or Powered) LJH: System, Irrigation, Urological OCX: Endoscopic Irrigation/Suction System HRX: Arthroscope

	GWG: Endoscope, neurological EOB: Nasopharyngoscope (flexible or rigid)
Predicate Device(s):	World of Medicine AQUILEX FLUID CONTROL SYSTEM H112 (K112624), Applied Medical EPIX (K122619), World of Medicine Uro Pro (K042457), Karl Storz Endomat LC (K031457), Atherex Dual Wave Arthroscopy Pump (K083707), Karl Storz ClearVision (K072410), Karl Storz Clear Vision (K013838) ***The above predicates have not been subject to any 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) 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, 5 l, sterilizable	20300050	Class II 510(k) Exempt
Cap for suction bottle 20 3000 50, 5 l sterilizable	20300034	Class II 510(k) Exempt
Metal filter	20300038	Class II 510(k) Exempt
Bottle stand for suction bottle, 5 I	20300032	Class II 510(k) Exempt
Bottle stand holder	20300033	Class II 510(k) Exempt
Suction bottle, 0,5 I, sterilizable	20300051	Class II 510(k) Exempt
Cap, for suction bottle	20300039	Class II 510(k) Exempt
Bottle stand, for suction bottle	20300231	Class II 510(k) Exempt
Control cable	20701070	Class II K973251
Single pedal footswitch	20014130	Class II K072410
SCB connecting cord, length 100 cm	20090170	Class II K994348
Tubing Set, Irrigation, PC, for single use, sterile, package of 10	031523-10	Class I
Tubing Set, Suction, BS, for	031647-10	Class I

	<table><tr><td>single use, sterile, package of 10</td><td></td><td></td></tr><tr><td>Tubing Set, Suction, OS, for single use, sterile, package of 10</td><td>030647-10</td><td>Class I</td></tr><tr><td>Tubing Set, Irrigation, FC, for single use, sterile, package of 10</td><td>031524-10</td><td>Class I</td></tr><tr><td>Tubing Set, Irrigation, CV, for single use, sterile, package of 10</td><td>031529-10</td><td>Class I</td></tr></table>
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 irrigations fluids, bodily fluids, secretions, tissue and gas during diagnostic and operative endoscopic urological procedures • provide liquid distention 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 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 *** The above Indications for Use represent a combination of the indications for the cited predicate devices and therefore there is no new intended use. ***
Technological Characteristics:	The proposed subject device is a multifunctional design that incorporates the functionality of multiple predicate devices. The technological differences between each of the subject device´s functions and the respective predicate devices are summarized in the Table 1.1. below, and they do not raise any different issues of safety and effectiveness.
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 o IEC 60601-1 o IEC 60601-1-2 o IEC 60601-1-8 • Software Verification and Validation Testing o *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* issued on May 11, 2005 o Level of Concern: Major • Summative Usability Testing o IEC 62366 • Performance Testing o *Hysteroscopic and Laparoscopic Insufflators: Submission Guidance For A 510(K)* issued on August 1, 1995 for Product Code HIG - Performance tests of pressure controlled irrigation mode

<table>
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- Performance tests of intrauterine pressure

Additional bench testing was performed to ensure the device met its design specifications.

<table>
<tr><th>Verification Test</th><th>Conclusion</th></tr>
<tr><td>Performance:
Pressure Control</td><td>Pass</td></tr>
<tr><td>Performance:
Flow Limitation</td><td>Pass</td></tr>
<tr><td>Performance:
Flow Control</td><td>Pass</td></tr>
<tr><td>Performance:
Pressure Limitation</td><td>Pass</td></tr>
<tr><td>Performance:
Suction Control</td><td>Pass</td></tr>
<tr><td>Safety:
Overpressure Warning (in pressure relevant GYN and URO interventions)</td><td>Pass</td></tr>
<tr><td>Safety:
Overpressure Warning (in pressure relevant ARTHRO interventions)</td><td>Pass</td></tr>
<tr><td>Safety:
Overpressure Alarm
(in pressure relevant GYN and URO interventions)</td><td>Pass</td></tr>
<tr><td>Safety:
Pressure Relief
(in pressure relevant GYN and URO interventions)</td><td>Pass</td></tr>
</table>

The bench testing performed verified and validated that the Endomat Select has met all its design specification and is substantially equivalent to its predicate devices.
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<td>Clinical
Performance Data:</td>
<td>Clinical testing was not required to demonstrate the substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to assess safety and effectiveness and to establish the substantial equivalence.</td>
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<td>Conclusion:</td>
<td>The non-clinical testing demonstrates that the device is as safe, as effective and performs as well as or better than the legally marketed predicate devices.</td>
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Table 1.1. Comparison of Technological Characteristics

	Subject Device	Predicate Devices by application						
	Karl Storz **Endomat Select**	**Applied Medical** **EPIX**	**World of Medicine** **AQUILEX FLUID CONTROL SYSTEM H112**	**World of Medicine** **Uro Pro**	**Karl Storz** **Endomat LC**	**Artherex** **Dual Wave Arthroscopy Pump**	**Karl Storz** **Clearvision**	**Karl Storz** **Clearvision Lens Irrigation System**
Application	**Multi**	**Surgery (Laparoscopy)**	**Hysteroscopic**	**Urological**	**Urological Suction**	**Arthroscopic**	**Lens Cleaning**	**Lens Cleaning**
								
Design	**Microprocessor controlled, pressure monitoring peristaltic Pump for irrigation or suction.**	Microprocessor controlled, peristaltic pump for irrigation with conduit for external suction.	Microprocessor controlled, pressure monitoring peristaltic pump for irrigation and/or suction.	Microprocessor controlled, pressure monitoring peristaltic pump for irrigation or suction.	Microprocessor controlled, peristaltic pump for suction.	Microprocessor controlled, pressure monitoring peristaltic pump for irrigation and suction.	Microprocessor controlled, oscillatory peristaltic pump	Microprocessor controlled, oscillatory peristaltic pump
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.	The Epix® Suction Irrigation System is intended as a general purpose suction and/or irrigation device for use in laparoscopic and open general surgery, laparoscopic and open gynecological surgery, laparoscopic and open urologic surgery. This device delivers sterile irrigant solution and serves as a conduit for suction.	Aquilex™ Fluid Control System is intended to provide liquid distension of the uterus during diagnostic and operative hysteroscopy, and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus.	The URO Pro is an irrigation roller pump intended for the infusion of sterile solutions into the ureter and upper urinary tract during diagnostic and/or therapeutic endoscopic urologic procedures. It is indicated for the infusion of sterile solutions through an endoscope into the urogenital tract to irrigate the ureter or upper urinary tract in a controlled manner and to improve visibility of the surgical field during urologic procedures.	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.	The AR-6480 is intended to provide continuous pulse-free flow that reacts immediately to changes in the intra-articular pressure so that joint distention can be sustained even under high shaver extraction volumes or secondary outflow.	Irrigation pumps and their accessories are used for the introduction of irrigation fluids into organs and perating fields during endoscopic interventions. The clearvision is a lens irrigation pump for the fields of ENT and Neurosurgery.	The KSEA Clearvision is a lens irrogation system for cleaning the lens and maintaining clear visualization without removing the scope from the surgical site during sinus surgery.

Procode	HIG, BTA, LJH, OCX, HRX, GWG, EOB	BTA	HIG	LJH	OCX	HRX	GWG	EOB
Pressure measurement location and	Yes, dual pressure sensors at the pump head	No pressure measurement	Yes, single transducer at the pump head	Yes, dual pressure sensors at the pump head	No pressure measurement	Yes, dual sensor	No pressure measurement	No pressure measurement
User interface/Selection of Application	LCD touch screen	Digital flowrate display and membrane buttons	igital display and buttor	Digital display and membrane buttons	Digital flowrate display and membrane buttons	LCD touch screen	On/Off	On/Off
Overpressure Safety	Yes, using software and roll pump reversal	No	Yes, using software and roll pump reversal	Yes, using software and roll pump reversal	N/A	Software controlled pump stops at >300mmHg (IFU recommends manual	N/A	N/A
Features								
Indicates Operating	Yes	No	Intrauterine	Yes	No	Yes	No	No
Alarm for over Pressure	Yes	No	Yes	Yes	No	Yes	No	No
Volume difference monitor	No	No	Yes	No	No	No	No	No
Indicates Operating Fluid Flow	Yes	Yes	No	Yes, nominal set point	No	No	No	No
Alarm for over Fluid Flow	Yes	No	Yes	Yes	No	No	No	No
Indicates Maximum Suction Pressure	No	No	No	No	No	No	No	No
Alarm for over Suction Pressure	No	No	No	No	No	No	No	No
Accessories								
Foot Switch	Yes	No	No	No	Yes	Yes	Yes	Yes
Tubing Sets	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
External pressure sensor (optional)	No	No	No	No	No	No	No	No

Performance								
Irrigation Pressure								
Lap/Surgical	100,300 and 500mmHg	Not Given						
Hysteroscopic	20-150mmHg		40-150 mmHg					
Urological	20-150mmHg			15-150 mmHg				
Urological suction	N/A				N/A			
Arthroscopy	20-150mmHg					10-120 mmHg		
Clearvision	N/A						N/A	
Clearvision	N/A							N/A
Irrigation Flow								
Lap/Surgical	100-3500ml/min	2, 3 or 4 L/min						
Hysteroscopic	200, 400, 600ml/min		0-800ml/min					
Urological	200, 400, 600ml/min			0-500ml/min				
Urological suction	N/A				N/A			
Arthroscopy	1500,2000,2500ml/min					0 - >1,500ml/min		
Clearvision	50,65,80,95,110,130ml/min						85 ml/min	
Clearvision	50,65,80,95,110,130ml/min							40 ml/min
Suction Pressure								
Lap/Surgical	N/A	N/A						
Hysteroscopic	N/A		- 500 mmHg					
Urological	N/A			N/A				
Urological suction	-0.95 Bar (-712.5mmHg)				-0.95 Bar (-712.5mmHg)			
Arthroscopy	N/A					Not Given		
Clearvision	N/A						N/A	
Clearvision	N/A							N/A
Suction Flow								
Lap/Surgical	N/A	N/A						
Hysteroscopic	N/A		N/A					
Urological Resection	0-1000ml/min			N/A				
Urological suction	300-1000ml/min				0-1000 ml/min			
Arthroscopy	N/A					N/A		
Clearvision	N/A						N/A	
Clearvision	N/A							N/A