DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 7, 2017

KARL STORZ Endoscopy America, Inc.
% Jack Rogers
Consultant
Safis Solutions LLC
303 N. Alabama, Suite 210
Indianapolis, IN 46204-2132

Re: K162992
Trade/Device Name: Karl Storz UROMAT E.A.S.I.
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: LJH
Dated: May 22, 2017
Received: May 24, 2017

Dear Jack Rogers:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162992

Device Name
Karl Storz UROMAT E.A.S.I

Indications for Use *(Describe)*

The UROMAT E.A.S.I. is used for the introduction of irrigation fluids into organs and operating fields as well as the suctioning off of irrigation and bodily fluids, secretions and tissue during endoscopic interventions.

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

1. Applicant Information

Karl Storz Endoscopy America, Inc.
2151 E. Grand Avenue
El Segundo, CA 90245

Contact Person: Serkan Sezer, VP Global Quality and Regulatory
Phone: 424-218-8201

Date Summary Prepared: September 22, 2016

2. Device/Classification

Device Trade Name:	Karl Storz Uromat E.A.S.I.
Common Name:	System, Irrigation, Urological
Classification:	21CFR 876.5130, Class 2 Urological catheter and accessories
Panel:	Gastroenterology/Urology
Product Code(s):	LJH

3. Predicate Devices

510(k) number:	K981615	K010569
Device Trade Name:	Karl Storz Uropump	Karl Storz Universal Laparomat
Common Name:	System, Irrigation, Urological	Laparoscope, General & Plastic Surgery
Classification:	21CFR 876.5130, Class 2 Urological catheter and accessories	21CFR 876.1500, Class 2 Endoscope and accessories
Panel:	Gastroenterology/Urology	General & Plastic Surgery
Product Code(s):	LJH	GCJ

4. Device Description

The UROMAT E.A.S.I. is a peristaltic (double roller), microprocessor controlled, irrigation and suction pump with continuous fluid flow for urological interventions. Alternatively, the two pumps can be flow-operated independently of each other for flow regulation, e.g., for laparoscopic interventions.

5. Intended Use / Indications for Use

The UROMAT E.A.S.I. is used for the introduction of irrigation fluids into organs and operating fields as well as the suctioning off of irrigation and bodily fluids, secretions and tissue during endoscopic interventions.

6. Comparison of Technological Characteristics with the Predicate Devices

Device	**Karl Storz UROMAT E.A.S.I.**	**Karl Storz UROPUMP**	**Karl Storz Universal Laparomat**
Basic Design	Peristaltic (double roller) pump; Microprocessor controlled	Peristaltic (single roller) pump; Microprocessor controlled	Gear pump; microprocessor controlled
Selection of Application(s)	Dual purpose pump for irrigation and suction: 1) continuous flow for urologic interventions; including use in lithotripsy (KS CALCUSON) 2) independent pump flow and regulation for laparoscopic interventions	Dual purpose pump for irrigation and suction, including when used in lithotripsy (KS CALCUSON)	Single mode
Overpressure Safety	Software does not allow pressure over 200 mm Hg (hardcode). Hardware alarm is triggered when the maximum pressure of 200 mm Hg is exceeded by 40 mm Hg.	Software alarm triggered when the present pressure setpoint value is exceeded by 20 mmHg. Hardware alarm is triggered when the maximum pressure of 200 mm Hg is exceeded by 40 mm Hg.	Electronic monitoring of the maximum output pressure via the torque of the gear pump. Double monitoring of the suction pressure.
Primary Pressure Measurement	Pressure sensor at the pressure dome measures the pressure at the pump output.	Pressure sensor at the pressure dome measures the pressure at the pump output.	Electronic monitoring of the maximum output pressure via the torque of the gear pump.
Irrigation Pressure	20…200mm Hg for Continuous Flow (CF), Single Flow (SF)	0 – 200 mm Hg	0 – 1800 mm Hg
Irrigation Flow	10…250 ml/min for Continuous Flow (CF)	0 – 400 ml/min	0 – 3000 ml/min (LAP)
Suction Pressure	N/A	Max -0.75 bar	0 – 800 mbar (LAP)
Suction Flow	100…1800 ml/min for Suction/Irrigation and Lithotripsy	0-1000 ml/min Suction flow rate is adjustable by the user and is preset before Uropump is used. Flow rate is key parameter for suction.	0 – (-)8 bar Suction under pressure
User Interface	Touch screen, digital display	Keys and LED bar graphs	Bar graph display

7. Performance Data – Nonclinical testing

The following test data were provided in support of the substantial equivalence determination:

- Uromat E.A.S.I.
    - Electrical safety and electromagnetic compatibility (EMC)
    - Software Verification and Validation Testing
    - Usability
- Tubing sets:
    - Biocompatibility including Cytotoxicity and Leachables/Extractability (Chemical Analysis)
    - Sterilization, shelf life and packaging verification and validation

8. Conclusion

The Karl Storz (KS) Uromat E.A.S.I. is substantially equivalent to the Karl Storz predicate devices.

The KS Uromat E.A.S.I. is substantially equivalent to the KS UROPUMP with regard to use and design characteristics. Both are used for irrigation and suction of fluids in ureteroscopic procedures.

The KS UROMAT E.A.S.I. is substantially equivalent to the KS KSEA Universal Laparomat with regard to use and design characteristics. Both are used for irrigation and suction of fluids in laparoscopic procedures.

Minor technological differences between the new and predicate devices do not raise any new concerns of safety and effectiveness.

The new device has the same intended use and operating principles, with similar design features, and functional and performance characteristics as the predicate devices. Based upon the performance data, it has been demonstrated that the Uromat E.A.S.I. performs as intended in the specified use conditions. The device is designed to comply with relevant federal and international safety and performance standards.