June 23, 2023

KARL STORZ Endoscopy America, Inc
Michael Block
Senior Manager, Regulatory Affairs International Submission
2151 E. Grand Avenue
El Segundo, California 90245

Re: K230359

Trade/Device Name: KOH Ultramicro Injection Cannula (26167NN); Suction a. Irrig. Cannula,L. 36cm (37360CP); Suction a. Irrig. Cannula,L. 36cm (37360SC); Suction and Irrig Cannula,l. 36cm (37560LH); Suction a. Irrig. Cannula,L. 30cm (37260LH); KOH Ultramicro Injection Needle (26167NA); Puncture Needle, LUER-lock (26178R); Suction a. Irrig. Cannula,L. 43cm (37460LH); Suction a. Irrig. Cannula,L. 36cm (37360LH); Puncture Needle, dia. 1.6 mm, 36 cm (26175R); Two-Way Stopcock (26167H); Injection Needle, LUER-lock (26178P); Injection Needle, dia. 1.2 mm, 36 cm (26175P); Ascites Suction Tube 11 mm (26120S); Suction and Irrigation Tube (26167ANS); Ascites Suction Tube (26175V); Suction and Irrigation Tube (26167ANL); Suction Tube w/ Protection Basket, 36 cm (26173BK); Suction and Irrigation Tube, size 3 mm (26167LHL); Suction and Irrigation Tube, size 3 mm (26167LH); Suction and Irrigation Tube, size 3 mm (26167LHS); Suction and Irrigation Tube, length 30cm (26172BN); Handle with Two-Way Stopcock (30805);

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope And Accessories

Regulatory Class: Class II

Product Code: GCJ, HET

Dated: February 10, 2023

Received: June 15, 2023

Dear Michael Block:

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; 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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.06.23 07:51:12 -04'00'

Mark Trumbore, Ph.D.
Assistant Director, THT4A1: Robotically-Assisted Surgical Devices Team
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

Device Name

KOH Ultramicro Injection Cannula (26167NN);
Suction a. Irrig. Cannula,L. 36cm (37360CP);
Suction a. Irrig. Cannula,L. 36cm (37360SC);
Suction and Irrig Cannula,l. 36cm (37560LH);
Suction a. Irrig. Cannula,L. 30cm (37260LH);
KOH Ultramicro Injection Needle (26167NA);
Puncture Needle, LUER-lock (26178R);
Suction a. Irrig. Cannula,L. 43cm (37460LH);
Suction a. Irrig. Cannula,L. 36cm (37360LH);
Puncture Needle, dia. 1.6 mm, 36 cm (26175R);
Two-Way Stopcock (26167H);
Injection Needle, LUER-lock (26178P);
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Suction and Irrigation Tube (26167ANL);
Suction Tube w/ Protection Basket, 36 cm (26173BK);
Suction and Irrigation Tube, size 3 mm (26167LHL);
Suction and Irrigation Tube, size 3 mm (26167LH);
Suction and Irrigation Tube, size 3 mm (26167LHS);
Suction and Irrigation Tube, length 30cm (26172BN);
Handle with Two-Way Stopcock (30805);
Suction and Irrigation Tube, 43 cm (26174BN);
Suction and Irrigation Tube, 36 cm (26173BN);
Suction and Irrigation Tube (40360LH)

Indications for Use *(Describe)*

The KARL STORZ suction and irrigation system (consisting of handle and suction/irrigation tubes, cannulae or needles) is intended for use by qualified surgeons to provide suction and/or irrigation function to help flush or remove blood, fluids, and tissue debris from the operation site during general, gynecologic, urologic, and thoracic laparoscopic surgical procedures.

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.

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. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Submitter:	KARL STORZ Endoscopy-America, Inc. 2151 E. Grand Avenue EI Segundo, CA 90245
Contact:	Michael Block Senior Manager, Regulatory Affairs International Submission KARL STORZ SE & Co. KG Email: michael.block@karlstorz.com Phone: +4916093781814
Date of Preparation:	February 10, 2023
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ Suction and Irrigation System
Common Name:	Suction and Irrigation System
Regulatory Class:	II
Product Code:	GCJ, HET
Classification Name:	21 CFR 876.1500 Endoscope and accessories 21 CFR 884.1720 Gynecologic laparoscope and accessories
Device Panel:	General & Plastic Surgery Obstetrics/Gynecology
Predicate Device(s):	Primary Predicate Device: KARL STORZ Suction/Irrigation Tubes, Cannulae, Sheaths, cleared via K945059. Secondary Predicate Device: KARL STORZ Puncture, Injection, Endoscopic, Veress Needle, cleared via K951190. These predicate devices have not been subject to a design-related recall.
Device Description:	The devices in the KARL STORZ Suction and Irrigation System are manually operated, reusable surgical devices consisting of handle, suction/irrigation tubes, cannulae or needles.

<table>
<tr><td></td><td>The handle is intended to be used in combination with suction/irrigation cannulae and tubing and controls the suction and irrigation. Enabled by the handle with stop cock valve, the regulation of the irrigated quantity of fluids via the tubes, or rather the quantity of aspirated fluid (e.g., blood, fluids, and tissue debris) into or out of the patient is performed.

Cannula and needle: Enabled by the pointed distal end, both puncture and injection/extraction cannulae and needles, perform puncturing of target organs or tissues and injecting fluids into operating site i.e. extracting blood or fluids from them.

The prerequisite for suction is either a vacuum powered suction wall apparatus or a pump, which serve as impulse for the suction. The proximal end of the tube set is connected to the vacuum or pump. Either a pump is required as impulse for irrigation or the natural force of gravity, i.e., by positioning the flush bag at the appropriate height.</td></tr>
<tr><td>Intended Use:</td><td>The KARL STORZ suction and irrigation system (consisting of handle and suction/irrigation tubes, cannulae or needles) is intended for use by qualified surgeons to provide suction and/or irrigation function to help flush or remove blood, fluids, and tissue debris from the operation site during general, gynecologic, urologic, and thoracic laparoscopic surgical procedures.</td></tr>
<tr><td>Indications For Use:</td><td>The KARL STORZ suction and irrigation system (consisting of handle and suction/irrigation tubes, cannulae or needles) is intended for use by qualified surgeons to provide suction and/or irrigation function to help flush or remove blood, fluids, and tissue debris from the operation site during general, gynecologic, urologic, and thoracic laparoscopic surgical procedures.</td></tr>
<tr><td>Patient Population</td><td>The KARL STORZ suction and irrigation system is intended to be used for adult population as well as pediatrics (same as Primary and Secondary Predicate Device).</td></tr>
<tr><td>Technological Characteristics:</td><td>Comparison Table: Subject vs. Primary and Secondary Predicate Devices
<table>
<tr><th></th><th>Subject Device</th><th>Primary Predicate Device (K945059)</th><th>Secondary Predicate Device (K951190)</th></tr>
<tr><td>Product Code</td><td>GCJ, HET</td><td>GCJ</td><td>HET</td></tr>
<tr><td>System Components</td><td>Handle and suction/irrigation</td><td>Handle and suction/irrigation</td><td>Injection needles, puncture</td></tr>
</table></td></tr>
</table>

		tubes, cannulae or needles	tubes, cannulae or sheaths	needles, endoscopic needles, biopsy needles and Veress needles
	Patient contacting materials	Surgical grade stainless steel	Same as subject	Same as subject
	Cleaning	Manual cleaning	Same as subject	Same as subject
	Sterilization Method(s)	Steam sterilization	Steam sterilization or Ethylene Oxide Sterilization	Steam sterilization or Ethylene Oxide Sterilization
	Construction	Dismountable	Non-dismountable	Non-dismountable

Non-Clinical Performance Data:

The following non-clinical performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The system complies with the following standards:

- ISO 10993

Reprocessing Validation Summary

The reprocessing data submitted complies with the following standards with regards to cleaning and sterilization:

- ANSI/AAMI/ISO 14937:2009
- ANSI/AAMI/ISO 11138-3:2017
- ANSI/AAMI/ISO 11607-1:2019
- ANSI/AAMI/ISO 11737-1:2018
- ANSI/AAMI ISO 17664
- ANSI/AAMI/ISO 17665-1:2006/(R)2013

Bench Top Performance Testing

Additional bench testing was performed to ensure the device met its design specifications and is substantially equivalent to its predicate devices.

- Leak Test

	• Flow Incoming Test • Flow Outcoming Test
Clinical Performance Data:	Clinical testing was not required to demonstrate the substantial equivalence to the predicate device. Non-clinical bench testing was sufficient to assess safety and effectiveness and to establish the substantial equivalence of the modifications.
Conclusion:	The conclusions drawn from the non-clinical performance data demonstrated that the subject device is as safe as and as effective as the primary and secondary predicate device. As such, we concluded that the substantial equivalence of the subject and the primary and secondary predicate devices has been met, and the differences between the subject and both predicate devices do not raise new questions of safety and effectiveness.