March 17, 2023

KARL STORZ Endoscopy America, Inc
Mario Trujillo
Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K221893
Trade/Device Name: KARL STORZ Bipolar Resectoscopes with HF Cable
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FJL, FAS, HIH, FDC
Dated: June 28, 2022
Received: February 13, 2023

Dear Mario Trujillo:

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,

Mark J. Antonino -S

Mark J. Antonino, M.S.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221893

Device Name
KARL STORZ Bipolar Resectoscopes with HF cable

Indications for Use *(Describe)*

The KARL STORZ bipolar resectoscopes with HF cable are intended for use by qualified surgeons for cutting, ablation, vaporization, and/or coagulation of tissue during various endoscopic urological procedures.

The following models are intended for the aforementioned use: 27040AK, 27040AO, 27040BK, 27040BO, 27040BP, 27040SD, 27040SL, 27040SM, 27040XA, 27040XB, 27050CA, 27050CB, 27050SC, 27050SD, 27050SL, 27050SM, 27050XA, 27050XB, 27051PL, 27051XA, 27054CB, 27054SC, 27054SL, 27054XB, 27241AO, 27241BK, 27241BO, 27040BB, 27040OA, 27040OB, 27040OC, 27040OD, 27048BK, 27048CK, 27048CO, 27050AE, 27050AK, 27050BE, 27050BK, 27051A, 27051B, 27054CO, PV27051B, 27040DB, 27040EO, 27040EB, 27040BL1 – S, 27040BLO1 – S, 27040GD1 – S, 27040GP1 – S, 27040GP130 – S, 27040GP140 – S, 27040GPB1 – S, 27040GPO1 – S, 27040JB1 – S, 27040JB130 – S, 27040JBE130 – S, 27040NB – S, 27040NBO – S, 27040VE – S.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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.

510(k) Number *(if known)*
K221893

Device Name
KARL STORZ Bipolar Resectoscopes with HF Cable

Indications for Use *(Describe)*

The KARL STORZ bipolar resectoscopes with HF cable are intended for use by qualified surgeons for cutting, ablation, vaporization, and/or coagulation of tissue during various endoscopic hysteroscopic electrosurgical procedures.

The following models are intended for the aforementioned use: 26040SL, 26040XA, 26050CA, 26050SC, 26050SL, 26050XA, 26053CB, 26053SC, 26055CB, 26055LD, 26055SC, 26055SL, 26055XB, 26055XE, 26053OC, 26055CO, 26040OC, 26053EB, 26040EB, 26055EB, 26040BL1-S, 26040GP1-S, 26040JB1-S, 26040NB-S, 26055BL1 - S, 26055GP1 - S, 26055NB- S.

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)

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K221893

Device Name
KARL STORZ Bipolar Resectoscopes with HF Cable

Indications for Use *(Describe)*

The KARL STORZ bipolar resectoscopes with HF cable are intended for use by qualified surgeons for cutting, ablation, vaporization, and/or coagulation of tissue during various endoscopic urological and hysteroscopic electrosurgical procedures.

The following models are intended for the aforementioned use: 011050-10, 011051-10, 011052-10, 011160-10, 011163-10, UH801.

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)

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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.

Submitter:	KARL STORZ SE & Co. KG Dr.-Karl-Storz-Straße 34 78532 Tuttlingen, Germany
Contact:	Mario Trujillo Regulatory Affairs Specialist Tel.: (424) 218-8481 Email: Mario.Trujillo@karlstorz.com
Date of Preparation:	June 23, 2022
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ Bipolar Resectoscopes with HF cable Common Name: Resectoscope (Product code FJL) Classification Name: Endoscope and Accessories (21 CFR Part 876.1500);
Regulatory Class:	2
Product Code:	FJL (FAS, HIH, FDC)
Guidance Document:	Not Applicable
Predicate Devices:	Resection Electrodes with HF cable (K210651)
Reference Devices:	KARL STORZ 27040 & 27050 Continuous Flow Resectoscopes (K882270) KSEA Bipolar Electrotome (K061541) KSEA Bipolar Electrode (K122983) KARL STORZ AUTOCON III 400 (K171717)
Device Description:	Resectoscopes are used for endoscopically controlled ablation of tissue. They are used for examination, diagnosis and/or therapy in conjunction with endoscopic accessories in medical disciplines such as Urology and Gynecology. A resectoscope is a combined cystoscope (urology) or hysteroscope (gynecology) and electrosurgical instruments and consists of a sheath, obturator, working element and HF electrode.

Indications For Use:	Indications for Use in UROLOGY: The KARL STORZ bipolar resectoscopes with HF cable are intended for use by qualified surgeons for cutting, ablation, vaporization, and/or coagulation of tissue during various endoscopic urological procedures. The following models are intended for the aforementioned use: 27040AK, 27040AO, 27040BK, 27040BO, 27040BP, 27040SD, 27040SL, 27040SM, 27040XA, 27040XB, 27050CA, 27050CB, 27050SC, 27050SD, 27050SL, 27050SM, 27050XA, 27050XB, 27051PL, 27051XA, 27054CB, 27054SC, 27054SL, 27054XB, 27241AO, 27241BK, 27241BO, 27040BB, 27040OA, 27040OB, 27040OC, 27040OD, 27048BK, 27048CK, 27048CO, 27050AE, 27050AK, 27050BE, 27050BK, 27051A, 27051B, 27054CO, PV27051B, 27040DB, 27040EO, 27040BL1 – S, 27040BLO1 – S, 27040GD1 – S, 27040GP1 – S, 27040GP130 – S, 27040GP140 – S, 27040GPB1 – S, 27040GPO1 – S, 27040JB1 – S, 27040JB130 – S, 27040JBE130 – S, 27040NB – S, 27040NBO – S, 27040VE – S. Indications for Use in GYNECOLOGY: The KARL STORZ bipolar resectoscopes with HF cable are intended for use by qualified surgeons for cutting, ablation, vaporization, and/or coagulation of tissue during various endoscopic hysteroscopic electrosurgical procedures The following models are intended for the aforementioned use: 26040SL, 26040XA, 26050CA, 26050SC, 26050SL, 26050XA, 26053CB, 26053SC, 26055CB, 26055LD, 26055SC, 26055SL, 26055XB, 26055XE, 26053OC, 26055CO, 26040OC, 26053EB, 26040EB, 26055EB, 26040BL1-S, 26040GP1-S, 26040JB1-S, 26040NB-S, 26055BL1 - S, 26055GP1 - S, 26055NB- S. Indications for Use in UROLOGY and GYNECOLOGY The KARL STORZ bipolar resectoscopes with HF cable are intended for use by qualified surgeons for cutting, ablation, vaporization, and/or coagulation of tissue during various endoscopic urological and hysteroscopic electrosurgical procedures. The following models are intended for the aforementioned use: 011050-10, 011051-10, 011052-10, 011160-10, 011163-10, UH801.

<table>
<tr><td>Technological Characteristics:</td><td>Comparison Table: Subject vs. Predicate Devices
<table>
<tr><th></th><th>Subject device
K221893</th><th>Predicate Device
K210651</th></tr>
<tr><td>Mode of ablation</td><td>Bipolar</td><td>Same as subject</td></tr>
<tr><td>Irrigation solution</td><td>Saline</td><td>Same as Subject</td></tr>
<tr><td>Working Length (mm)</td><td>184,7 – 270</td><td>261.8 – 336.7</td></tr>
<tr><td>Compatible scope shaft diameter (FR)</td><td>15 – 28</td><td>24</td></tr>
<tr><td>Electrode Active tip shapes</td><td>Loop, needle, roller, button</td><td>Loop, band, needle, roller, button</td></tr>
<tr><td>Electrode Active tip designs</td><td>55° - 135°</td><td>12° - 30° angles</td></tr>
<tr><td>Stabilizing tube diameter (mm)</td><td>4.95 – 9.6 mm</td><td>4.1</td></tr>
<tr><td>HF Cables packaged with device</td><td>Yes</td><td>Same as subject</td></tr>
<tr><td>Shelf life</td><td>3 years</td><td>Same as subject</td></tr>
</table></td></tr>
<tr><td>Non-Clinical Performance Data:</td><td>There are no performance standards or special controls developed under Section 514 of the FD&C Act for endoscopes. However, the subject device follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance:
Electrical Safety and EMC
IEC 60601-1
IEC 60601-1-2
IEC 60601-2-18
ISO 10993
Performance Testing
Attachment/Detachment force of the electrode
System Interlocking Test
Flow Test (comparative)
Bending Force Test
HF Tissue and HF Durability Test
Additional bench testing was performed to ensure the device met its design specifications. The bench testing performed verified and validated that the KARL STORZ Bipolar Resectoscope has met all its design specification and is substantially equivalent to the predicate device.</td></tr>
<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 KARL STORZ Bipolar Resectoscope, performs as well as or better than devices that are currently marketed for the same intended use.</td></tr>
</table>