April 27, 2023

Karl Storz-Endoscopy-America, Inc.
Alita McElroy
Senior Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K223520
Trade/Device Name: UNIDRIVE SIII System
Regulation Number: 21 CFR§ 884.1690
Regulation Name: Hysteroscope and Accessories
Regulatory Class: II
Product Code: HIH
Dated: March 27, 2023
Received: March 28, 2023

Dear Alita McElroy:

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 Roberts -S

Jason R. Roberts, Ph.D.
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)*
K223520

Device Name
UNIDRIVE SIII System

Indications for Use *(Describe)*
The UNIDRIVE SIII System is intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue.

The HOPKINS Telescope when used with the obturator is intended to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and 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.

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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. 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:	Alita McElroy Senior Regulatory Affairs Specialist Phone: (424) 218-8376 Email: Alita.McElroy@karlstorz.com
Date of Preparation:	April 26, 2023
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: UNIDRIVE SIII System Classification Name: Hysteroscope and accessories (21 CFR 884.1690)
Regulatory Class:	II
Product Code:	HIH
Classification Panel:	Obstetrics/Gynecology
Predicate Device(s):	Primary Predicate: TRUCLEAR Morcellator System and TRUCLEAR Morcellators (K132015) *The primary predicate has been subject to a design related recall* Secondary Predicate: KARL STORZ Magnifying Hysteroscopes (K935716) *The secondary predicate has not been subject to any recall*
Device Description:	The UNIDRIVE® SIII system is a motorized surgical device intended for intrauterine use to hysteroscopically resect and remove tissue. The UNIDRIVE SIII System includes the following components: • UNIDRIVE SIII Control Unit (20701020-1) • Footswitch (20016230) • DrillCut-X II Shaver handpiece GYN (26702050) • Shaver blades (26208SA, 26208SB) • HOPKINS Telescope (26208AMA) • Obturator (26208OC)

	The UNIDRIVE S III system has a motor control unit and can be used with the DrillCut-X II Shaver handpiece GYN which houses the shaver blades. The shaver blade upon being connected to the DrillCut-X II Shaver handpiece GYN is inserted into the working channel of the HOPKINS Telescopes. The shaver blades are activated via a one-pedal footswitch that is connected the UNIDRIVE SIII control unit. The shaver blades consist of two sheaths that fit into each other. The inner sheath oscillates within the outer sheath to enable tissue resection.
Indications for Use:	The UNIDRIVE S III System is intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue. The HOPKINS Telescope when used with the obturator is intended to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and surgical procedures.
Technological Characteristics.	The subject device, UNIDRIVE SIII System is substantially equivalent to the TRUCLEAR Morcellator System and TRUCLEAR Morcellators, (510(k) Number: K132015), marketed by Medtronic as well as to secondary predicate KARL STORZ Magnifying Hysteroscopes (510(k) Number: K935716). The subject and primary predicate devices are intended for intrauterine use for resection and removal of tissue. The main differences between the subject and primary predicate devices include the following: • The subject device includes a control unit, footswitch shaver handpiece, shaver blade, hysteroscope and an obturator while the primary predicate does not include a hysteroscope and obturator but includes other common components as the subject device. However the primary predicate device requires a hysteroscope to achieve its intended use similar to the subject device. • The subject device includes oscillating shaver blades and has a default rotational speed of 2100rpm and maximum rotational speed of 5000rpm. The primary predicate device includes oscillating shaver blade and reciprocating shaver blade. When used with the oscillating shaver blade, primary predicate device has a default rotational speed of 800rpm and maximum speed of 1500rpm. When used with the reciprocating blade, the primary predicate device has a default rotational speed of 1100rpm and maximum speed of 2500rpm.

	• The subject device shaver handpiece and shaver blades are provided non-sterile and are reusable while the primary predicate include sterile single-use shaver handpiece and shaver blades. The secondary predicate is chosen to support the diagnostic and surgical hysteroscopic indications of the subject device. Both the subject device and secondary predicate device include reusable rigid rod-lens scopes that are used with external light sources a light cable, a camera head, and/or a Camera Control Unit (CCU). The subject device endoscope includes a working length of 21cm while the secondary predicate endoscopes have working length in the range of 18.5cm-30cm. The main differences between the subject and secondary predicate devices include the following: • The outer diameter of the subject device is 7.3mm and the secondary predicate includes endoscopes with outer diameters that ranges from 2.4mm to 4mm. • The subject device includes an endoscope with 6° direction of views while the secondary predicate device includes endoscopes with direction of view of 0°, 30°, 45°, 70° & 120°. • The subject device endoscope has a field of view of 105° ± 3° whereas the secondary predicate device includes endoscopes with a field of view of 67°- 92° ± 4°. • The subject device endoscope has a working channel diameter of 4.3mm while the secondary predicate endoscopes do not have a working channel.
Non-Clinical Performance Data:	There are no performance standards or special controls developed under Section 514 of the FD&C Act for the UNIDRIVE SIII System. However, the UNIDRIVE SIII System follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance: **Hysteroscopes and Gynecologic Laparoscopes Guidance** • Hysteroscopes and Gynecologic Laparoscopes - Submission Guidance for a 510(k) **ISO Endoscopic Standards** • ISO 8600-1:2015 • ISO 8600-3:2019 • ISO 8600-5:2020

	Biocompatibility Summary • Cytotoxicity (ISO 10993-5) • Acute Systemic Toxicity (ISO 10993-11) • Intracutaneous Irritation (ISO 10993-10) • Maximization Sensitization (ISO 10993-10) **Electrical Safety and EMC** • IEC 60601-1:2012 (3rd Edition) • IEC 60601-2-18:2009 (3RD Edition) • IEC 60601-1-2:2014 (4th Edition) **Reprocessing (Cleaning and Sterilization)** • AAMI TIR12: 2010 • AAMI TIR30: 2011 • AAMI TIR39: 2009 • ANSI/AAMI ST8: 2013 • ANSI/AAMI ST77:2013 • ANSI/AAMI ST79:2017 • ANSI/AAMI ST81:2004/(R)2010 • AAMI/ISO 14937:2009 • ANSI/AAMI/ISO 17655-1:2006/2013 • ANSI/AAMI/ISO 17655-2:2009 • Reprocessing Medical Device in Health Care Settings: Validation Methods and Labeling **Software Verification and Validation Testing** • Guidance for the Content of Premarket Submissions for Software Contained in Medical Device The cutting performance of the subject device, UNIDRIVE SIII system has been successfully demonstrated by comparing to the primary predicate device TRUCLEAR Morcellator System and TRUCLEAR Morcellators cleared in K132015. Additional comparative bench testing between the subject and secondary predicate device was conducted to demonstrate the optical performance of the HOPKINS Telescope that is part of the subject UNIDRIVE SIII system to meet its intended use.
Clinical Performance Data:	Clinical Testing was not required to demonstrate the substantial equivalence to the predicate devices. Non-clinical testing was adequate to establish substantial equivalence.

Conclusion:	The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe and effective as the primary and secondary predicate devices to support a substantial equivalence determination.