October 22, 2020

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

Re: K200318
Trade/Device Name: UNIDRIVE S II ENT, DrillCut-X II-35 Shaver Handpiece, DrillCut-X II-35 N Shaver Handpiece
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, nose, and throat electric or pneumatic surgical drill
Regulatory Class: Class II
Product Code: ERL
Dated: July 21, 2020
Received: July 23, 2020

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,

Joyce C. Lin -S

for Malvina Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200318

Device Name
UNIDRIVE S III ENT

Indications for Use *(Describe)*
The UNIDRIVE® S III ENT system consists of an active control unit used in conjunction with the High-Speed Micro Motor and DrillCut-X® II Shaver handpieces. The system is intended for use by qualified surgeons to provide controlled cutting, drilling, debriding, sawing, and shaving for the ablation, excision, removal, or transection of tissue or bone during head, neck, ENT, or otoneurological 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.

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K200318 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 Regulatory Affairs Specialist Phone: (424) 218-8376 Fax: (424) 218-8519
Date of Preparation:	October 22, 2020
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: UNIDRIVE S III ENT Classification Name: Drill, Surgical, ENT (Electric Or Pneumatic) Including Handpiece
Regulatory Class:	II
Product Code:	ERL
Regulation:	21 CFR 874.4250 (Ear, nose and throat electric or pneumatic surgical drill)
Predicate Device(s):	Predicate Device: UNIDRIVE S III ENT (K150969) *The predicate device has not been subject to a design-related recall.*
Device Description:	The UNIDRIVE S III ENT is a motorized surgical device system used for the excision, ablation, removal or transection of bones/tissues during head, neck, ENT, or otoneurological surgical procedures. The system components include a control unit used in conjunction with the High-Speed Micro Motor that houses the high-speed handpieces and DrillCut-X® II Shaver handpieces. The modifications made to the UNIDRIVE® S III ENT system is the addition of the DrillCut-X® II-35 and DrillCut-X® II-35 N Shaver handpieces. Additional accessories used with the UNIDRIVE S III ENT system include the shaver blades, sinus burrs and the sinus burr 35k.

Intended Use:	The UNIDRIVE S III ENT system consists of an active control unit used in conjunction with the High-Speed Micro Motor and DrillCut-X® II Shaver handpieces. The system is intended for use by qualified surgeons to provide controlled cutting, drilling, debriding, sawing, and shaving for the ablation, excision, removal, or transection of tissue or bone during head, neck, ENT, or otoneurological surgical procedures.
Indications For Use:	The UNIDRIVE S III ENT system consists of an active control unit used in conjunction with the High-Speed Micro Motor and DrillCut-X® II Shaver handpieces. The system is intended for use by qualified surgeons to provide controlled cutting, drilling, debriding, sawing, and shaving for the ablation, excision, removal, or transection of tissue or bone during head, neck, ENT, or otoneurological surgical procedures.
Technological Characteristics:	The UNIDRIVE S III ENT is a modification of and substantially equivalent to the UNIDRIVE S III ENT (K150969) in terms of its indication for use, principle of operation, patient-contacting materials and reprocessing methods. The subject device includes the addition of the DrillCut-X® II-35 and DrillCut-X® II-35 N Shaver handpieces that have a maximum rotational speed of 35,000 RPM in comparison with the shaver handpieces of the predicate device that have a maximum rotational speed of 12,000 RPM.
Non-Clinical Performance Data:	The device has been tested and passed the electrical safety testing and EMC testing, which is certified to be Class I protection against electrical shock. The UNIDRIVE S III ENT system follows the FDA recognized consensus standards and is tested according to the following standards: • IEC 60601-1 • IEC 60601-1-2 • ISO 14971 • ISO 10993 •

	Cleaning and sterilization validations were conducted for patient-contacting components. The reprocessing data submitted complies with the following standards: • ANSI/AAMI ST81:2004/(R) 2010 • ANSI/AAMI ST79: 2010/A4:2013 • AAMI TIR 12:2010 • ANSI/AAMI/ISO 17665-1:2006 • ANSI/AAMI/ISO 17665-2:2009 • AAMI TIR 39:2009 The following bench testing was performed to ensure that the UNIDRIVE S III ENT system meets its design specification • Inspection of rotation speed and torque Bench testing demonstrated substantial equivalence to the predicate device.
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.
Substantial Equivalence:	The conclusions drawn from the nonclinical test such as the risk evaluation on the modification of the system, biological evaluation summary, cleaning and sterilization summary demonstrated that the subject device is as safe and as effective as the predicate device. Both systems also comply with identical standards and safety testing, where applicable. As such, we concluded that the substantial equivalence of the subject and the predicate device has been met, and the differences between the subject and predicate do not raise new questions of safety and effectiveness.