



Food and Drug Administration
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January 8, 2016

Karl Storz Endoscopy America, Inc.
Jennifer Chambers
Regulatory Affairs Specialist
2151 E. Grand Ave
El Segundo, California 90245

Re: K150969

Trade/Device Name: Unidrive S Ili Ent 40701601-1 With Karl Storz-scb, Drillcut-x II
Shaver Handpiece, High Speed Ec Micromotor II For Use With Intra
Drill Handpieces

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: December 4, 2015

Received: December 8, 2015

Dear Ms. Chambers:

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 yours,

Eric A. Mann -S

Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

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 handpiece. 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.

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7. 510(k) Summary

Traditional Premarket Notification Submission (510(k)) Summary
Prepared in accordance with 21 CFR 807.92

7.1 Submitter Information

Sponsor name: KARL STORZ Endoscopy America, Inc.
Sponsor address: 2151 E. Grand Ave.
El Segundo, CA 90245 USA
Sponsor telephone: 424-218-8100
Sponsor fax: 424-218-8519
Establishment Registration: 3010202439

Contact person: Jennifer Michelle Chambers
MPA, MBA, CCRP, CQA, PMP, RAC (US)
Contact title: Regulatory Affairs Specialist
Email direct: jennifer.chambers@karlstorz.com
Telephone direct: 424-218-8457
Date summary prepared: March 31, 2015
Date summary updated: January 5, 2016

7.2 Device Name

Trade (proprietary): UNIDRIVE S III ENT
Common (usual): Drill, Surgical, ENT (Electric Or Pneumatic) Including Handpiece
Classification: 21 CFR 874.4250 (Class II)
FDA Device Code: ERL: Ear, nose, and throat electric or pneumatic surgical drill
Review Panel: 77 (Ear Nose & Throat)

7.3 Substantially Equivalent Predicate Device

Device Name: KSEA UNIDRIVE ENT System and Accessories
Device 510(k): K053262

7.4 Device Description

The UNIDRIVE[®] S III ENT is a motorized surgical device system, consisting of an active control unit used in combination with: the High-Speed Micro Motor and attaching handpiece and the DrillCut-X[®] II Shaver handpiece (with optional attaching handle). The surgical device system provides 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.

7.5 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 handpiece. 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.

7.6 Technological Characteristics

The UNIDRIVE® S III ENT system and the predicate UNIDRIVE ENT system are both motorized, reusable surgical device systems, used in conjunction with drills, handpieces, blades, and burs. Both systems provide controlled cutting, drilling, sawing, and removal of bone during head, neck, ENT, and or otoneurological surgical procedures. The performance of the new device has undergone system verification and validation testing to ensure it does not introduce new issues of safety or effectiveness.

7.7 Performance Characteristics

Nonclinical performance characteristics evaluated in support of the substantial equivalence of the UNIDRIVE® S III ENT include system verification and validation testing. Study results demonstrate adherence to design specifications. Experiments yielded consistent results. Consistent test conditions were maintained throughout the study. Performance testing reports are provided in the Performance Testing (Bench) of this 510(k). Cleaning and sterilization validations were conducted for patient-contacting components.

7.8 Cleaning and Sterilization

Reusable instruments (i.e. DrillCut-X® II Shaver handpiece, High-Speed Micro Motor and handpieces, plus compatible Straight Shaver Blades) are delivered non-sterile and must be cleaned and sterilized prior to the initial use and before each subsequent use. Compatible sinus burrs and disposable tubings are sterile, single-use products and must be disposed of after patient use. Sterility efficacy demonstrated a sterility assurance level of 10^{-6} in a pre-vacuum steam sterilizer. Manual cleaning effectiveness was demonstrated with sufficient recovery efficiency for residual protein and residual hemoglobin.

7.9 Animal and Clinical Performance Data:

Animal and Clinical performance data are not required to demonstrate substantial equivalence for this type of device.

7.10 Conclusion

Based on the information provided in this premarket notification, KARL STORZ concludes that the UNIDRIVE® S III ENT is safe, effective, and substantially equivalent to the predicate UNIDRIVE ENT in its indication for use, device design, materials, performance characteristics, and operational principles.