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K053262

DEC 19 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information 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.

Applicant: Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 338-8100

Contact: Yvonne Fernandez/Sr. Regulatory Affairs Specialist

Device Identification: Common Name: Surgical ENT Shaver/ENT Drill
Trade Name: UNIDRIVE ENT & Accessories

Indications: The KSEA Paranasal Sinus Shaver, Micro Shaver or Stammberger-Castelnuovo DrillCut-X Shaver in conjunction with the UNIDRIVE ENT control unit is a motorized, reusable surgical device system, intended for use by qualified surgeons to shave, debride, or cut tissue during Head, Neck, ENT and Otoneurological surgical procedures. The KSEA Stammberger-Sachse Intranasal Drill or the INTRA Drill in conjunction with the UNIDRIVE ENT control unit is a motorized, reusable surgical device system, intended for use by qualified surgeons to provide controlled cutting and removal of bone during Head, Neck, ENT and Otoneurological surgical procedures.

Device Description: The UNIDRIVE ENT System is a motorized, reusable surgical device system that can be used in conjunction with Stammberger Paranasal Sinus Shaver, Micro Shaver, Stammberger-Castelnuovo DrillCut-X Shaver, Stammberger-Sachse Intranasal Drill and INTRA Drill.

Substantial Equivalence: The KSEA Stammberger Paranasal Sinus Shaver, Micro Shaver, Stammberger-Castelnuovo DrillCut-X Shaver, Stammberger-Sachse Intranasal Drill and INTRA Drill are substantially equivalent to the predicate devices since the basic features, design and intended uses are similar. The minor differences in design and dimensions between the subject devices and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function or intended use of these devices.

TABLE 1: SUBSTANTIAL EQUIVALENCE TABLE FOR ENT SHAVER BLADES AND CUTTERS

Device	UNIDRIVE ENT Shaver Handpieces	UNIDRIVE II/II PLUS (K003994) Paranasal Sinus Shaver Handpiece	XPS 3000 (K041413) Magnum II/M4 Microresector
Basic Features	Handpiece w/Suction Control Unit w/Footswitch Straight or Angled (90°) Design	Same Same Angled (90°) Design	Same Same Straight/"Sculpted"
Maximum Speed (rpm)/ Modes	3,500 - 12,000/FWD-REV; 3,000 - 7,000/OSC	3,000/FWD;REV;OSC	15,000/FWD;REV 5,000/OSC
Blade/ Sinus Burr Dimensions	O.D.: 3.0 - 5.0 mm Lengths: 12 cm	O.D.: 2.0 - 4.0 mm Lengths: 7-12 cm	O.D.: 2.0 - 6.0 mm Lengths: unknown
Autoclavable	Yes	Yes	Yes
Body Contacting Material	Stainless steel	Same	Stainless steel and medical polymer
Intended Use	To shave, debride or cut tissue during Head, Neck, ENT and Otoneurological surgical procedures.	To shave, debride or cut tissue during ENT endoscopic surgical procedures.	Shaving, debridement and cutting of soft tissue and bone during Head, Neck, ENT, Otoneurological, Aesthetic and Arthroscopic surgical procedures.

TABLE 2: SUBSTANTIAL EQUIVALENCE TABLE FOR STAMMBERGER SACHSE INTRANASAL DRILL

Device	UNIDRIVE ENT Intranasal Drill	UNIDRIVE II/II PLUS (K003994) Intranasal Drill	XPS 3000 Bone Drill (K002224)
Basic Features	Handpiece w/Suction Control Unit w/Footswitch Straight or Angled (90°) Design	Same Same Angled (90°) Design	Same Same Angled Design
Maximum Speed (rpm)	60,000	20,000	80,000
Abrader Dimensions	Diameters: 2.5 - 5.0 mm	Diameters: 2.5 - 3.0 mm	Unavailable
Autoclavable	Yes	Yes	Yes
Body Contacting Material	Surgical grade stainless steel; diamond dust covered heads	Same	Titanium; aluminum coated with fluoroplastic/carbide; diamond dust
Intended Use	To provide controlled cutting and removal of bone tissue during Head, Neck, ENT and Otoneurological surgical procedures.	To provide controlled cutting and removal of bone tissue during ENT procedures.	To provide controlled shaving, debridement, cutting and removal of soft and bone tissue during Head, Neck, ENT and Otoneurological surgical procedures.

TABLE 3: SUBSTANTIAL EQUIVALENCE TABLE FOR DRILLS

Device	UNIDRIVE ENT INTRA Drill Handle	UNIDRIVE II/II PLUS (K003994) ENT Drill	XPS 3000 Bone Drill (K002224)
Basic Features	Handpiece w/Suction Control Unit w/Footswitch Angled (90°) Design	Same Same Straight or Angled Design	Same Same Angled Design
Maximum Speed (rpm)	40,000	40,000	80,000
Abrader/Burr Dimensions	Diameters: 0.6 - 7.0 mm Lengths: 5.7- 12.5 cm	Diameters: 0.6 - 7.0 mm Length: 5.7- 12.5 cm	Unavailable
Body Contacting Material	Surgical grade stainless steel; tungsten carbide; diamond dust	Surgical grade stainless steel; tungsten carbide; diamond dust	Titanium; aluminum coated with fluoroplastic/carbide; diamond dust
Intended Use	To provide controlled cutting and removal of bone tissue during Head, Neck, ENT and Otoneurological surgical procedures.	To provide controlled cutting and removal of bone tissue during ENT endoscopic surgical procedures.	To provide controlled shaving, debridement, cutting and removal of soft and bone tissue during Head, Neck, ENT and Otoneurological surgical procedures.

Signed: 

Yvonne Fernandez
Sr. Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2005

Karl Storz Endoscopy-America, Inc.
c/o Ivonne Fernandez
Sr. Regulatory Affairs Specialist
600 Corporate Pointe 5th Floor
Culver City, California 90230

Re: K053262
Trade/Device Name: KSEA Unidrive ENT System and Accessories
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: November 18, 2005
Received: November 22, 2005

Dear Ms. Fernandez:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

KARL STORZ ENDOSCOPY

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510(k) Number (if known): K053262

Device Name: UNIDRIVE ENT System and Accessories

Indications for Use:

The STAMMBERGER Paranasal Shaver 90° Handpiece, the straight Micro-Shaver Handpiece, or the STAMMBERGER-CASTELNUOVO DrillCut-X Shaver Handpiece in conjunction with the UNIDRIVE ENT control unit is a motorized, reusable surgical device system, intended for use by qualified surgeons to shave, debride or cut tissue during Head, Neck, ENT and Otoneurological surgical procedures.

The KSEA Stammberger-Sachse Intranasal Drill or ENT Drill in conjunction with the UNIDRIVE ENT control unit is a motorized, reusable surgical device system, intended for use by qualified surgeons to provide controlled cutting, drilling, sawing and removal of bone during Head, Neck, ENT and Otoneurological surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

K053262