



KARL STORZ
Endoscopy-America, Inc.

2151 E. Grand Avenue
El Segundo, California 90245

Toll Free 800 421 0837
Fax 800 321 1304

NOV 15 2010

K093054

510(k) SUMMARY

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 are accurate and complete to the best of KSEA's knowledge.

Submitter: Karl Storz Endoscopy-America, Inc.
2151 E. Grand Avenue
El Segundo, CA 90245-5017
Phone: (424) 218-8381
Fax: (424) 218-8519

Contact Person: Crystal Dizol
Regulatory Affairs Specialist
Email: cdizol@ksea.com

Date Prepared: April 29, 2010

Device Trade Name: Karl Storz Scalp Dura Retractor

Common Name: Retractor, Self-retaining

Classification Name: Self-retaining retractor for neurosurgery.

Regulation Number: 21 CFR 882.4800

Product Code: GZT

Predicate Device(s):
KLS-Martin, LP: Grossman Self-retaining Low Profile Brain Retractor (K060097)
Ohio Medical Instrument Co.: TEW Cranial/Spinal Retractor Model A 1090 (K960807)
Ohio Medical Instrument Co.: BUDDE Halo Retractor (K830332)

Device Description:
The Karl Storz Scalp Dura Retractor is a non-powered, manual, adjustable, self-retaining retractor for neurosurgery. The assembly comprises a retractor handle, a stationary blade, a telescope sheath/cannula, and an adjustable/movable blade. One knob controls the telescoping of the stationary blade and a second knob controls the angular opening of the adjustable blade. The telescope cannula allows for the introduction of an endoscope for direct visualization of the surgical site.

Intended Use:

The Karl Storz Scalp Dura Retractor is intended for use to elevate dura and scalp layers away from cranial bone during endoscopic-assisted strip craniectomies.

Technological Characteristics:

The primary difference between the Karl Storz Scalp Dura Retractor and the predicate devices is the design of the mechanism that allows for adjustability of the retractor blades. The retractor blades of the predicate devices are mounted on segmented flexible arms that allow the user to position the arms over a range of configurations in three dimensions. The retractor blades of the Karl Storz Scalp Dura Retractor are mounted to provide retraction configurations in a single plane. Differences in design exist to support the specific indication for use and do not raise any new issues of safety and effectiveness. For a summary of technological characteristics of the Karl Storz Scalp Dura Retractor as compared to the predicate devices, please refer to the attached substantial equivalence table.

Mechanical Testing:

The Karl Storz Scalp Dura Retractor demonstrated mechanical equivalence by a load deflection test, in which the device was loaded and the lateral deflection was measured. The deflection displacements were found to be substantially equivalent to the predicate Tew Cranial Spinal Retractor Model A as well as the Budde-Halo Retractor.

Reprocessing Instructions for Health Care Facilities:

The labeling for the Karl Storz Scalp Dura Retractor includes validated cleaning instructions and device sterilization by steam (pre-vacuum) for reprocessing in health care facilities in accordance with "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance" (available at <http://www.fda.gov/cdrh/ode/198.pdf>) and AAMI TIR 12:2004, "Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers."

Determination of Substantial Equivalence:

The Karl Storz Scalp Dura Retractor is substantially equivalent to the predicate devices. Where differences in performance or technology exist, it has been demonstrated that they do not adversely impact safety or effectiveness. In addition, the Karl Storz Scalp Dura Retractor has been tested to validate its use for the specific intended use of elevating dura and scalp layers away from cranial bone during endoscopic-assisted strip craniectomies. The Karl Storz Scalp Dura Retractor and its predicate devices are reusable and sterilizable non-powered, manual, adjustable, self-retaining retractors for use during neurosurgical procedures.

Conclusions:

The Karl Storz Scalp Dura Retractor is substantially equivalent to the identified predicate devices and does not raise any new issues of safety and efficacy.

Att: Substantial Equivalence Table for Karl Storz Scalp Dura Retractor

SUBSTANTIAL EQUIVALENCE TABLE FOR KARL STORZ SCALP DURA RETRACTOR

| Manufacturer | Description | Material | Usability | Predicates | Intended Use |
|---|--|-----------------|------------------------|--|---|
| Karl Storz Scalp Dura Retractor | Non-powered, manual, self-retaining retractor with handle-mounted retractor blades for retraction configurations in a single plane. | Stainless steel | Reusable, Sterilizable | See below | To elevate dura and scalp layers away from cranial bone during endoscopic-assisted strip craniectomies. |
| KLS-Martin, LP: Grossman Self-Retaining Low Profile Brain Retractor (K060097) | Non-powered, manual, self-retaining retractor with retraction blades mounted on flexible segmented arms for retraction in any three-dimensional configuration. | Same | Same | Tew Cranial/Spinal Retractor Model A 1090 (K960807) Budde®-Halo Retractor (K830332) | To retract soft tissue during neurosurgical procedures. |
| Ohio Medical Instrument Co.: Tew Cranial/Spinal Retractor Model A 1090 (K960807) | Non-powered, manual, self-retaining retractor with frame retractor for planar skin or muscle retraction and flexible micro-retractor arms for retraction in any three-dimensional configuration. | Same | Same | Karlin Crank Frame Spinal Retractor Set (K882071) Apfelbaum Cerebellar Retractor Budde®-Halo Retractor (K830332) | For posterior fossa or intraspinal microsurgery where retraction is required. |
| Ohio Medical Instrument Co.: Budde®-Halo Retractor (K830332) | Non-powered, manual, self-retaining retractor with frame retractor to support flexible segmented retractor arms for retraction in any three-dimensional configuration. | Same | Same | Unknown | For mounting and positioning flexible arms for retracting membranes, particularly of the brain, during surgical operations. |



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Karl Storz Endoscopy-America, Inc.
c/o Ms. Crystal (Dizol) Hagan
Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, CA 90245

Re: K093054

NOV 15 2010

Trade/Device Name: Scalp Dura Retractor, Model KS00474
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-Retaining Retractor For Neurosurgery
Regulatory Class: Class II
Product Code: GZT
Dated: November 5, 2010
Received: November 8, 2010

Dear Ms. Hagan:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K093054

INDICATIONS FOR USE

NOV 15 2010

510(k) Number (if known): Not yet assigned

Device Name: Karl Storz Scalp Dura Retractor

Indications for Use: The Karl Storz Scalp Dura Retractor is intended for use to elevate dura and scalp layers away from cranial bone during endoscopic-assisted strip craniectomies.

Prescription Use: X AND/OR Over-The-Counter Use:
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

JEFFREY TOY
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

Page 1 of

510(k) Number K093054