KARL STORZ — ENDOSKOPE

JUN 2 6 2013

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

Applicant: KARL STORZ Endoscopy – America, Inc.
2151 E. Grand Ave
El Segundo, CA 90245
(424) 218-8379 Tel
(424) 218-8519 Fax

Contact: Winkie Wong
Regulatory Affairs Specialist

Date: September 14, 2012

Device Identification:

Common Name: Bipolar Electrode

Classification Name: Coagulator-Cutter, Endoscopic, Bipolar (And Accessories) [21 CFR 884.4150, Product Code HIN]

Trade Name: (optional) The Karl Storz Bipolar Electrode

Device Description: The Karl Storz Bipolar Electrode is a single-use cutting loop electrode that is designed to be used in combination with a 4 mm resectoscope with a 24 or 26 Fr sheath that is connected to a generator via a high frequency cable.

Indications: The Karl Storz Bipolar Electrode is intended for use in tissue cutting, removal and desiccation as required or encountered in gynecologic hysteroscopic electrosurgical procedures for the treatment of intrauterine myomas, polyps, adhesions and septa, and benign conditions requiring endometrial ablation. Procedures include:

Excision of intrauterine myomas
Excision of intrauterine polyps
Lysis of intrauterine adhesions
Incision of uterine septa
Endometrial ablation

KARL STORZ—ENDOSKOPE

Contraindications: The Karl Storz Bipolar Electrode must not be used if the patient's health is endangered due to general condition of the patient, or if the endoscopic method as such is contraindicated.

Karl Storz Bipolar Electrodes are not intended for use in tubal sterilization procedures. The use of this device is contraindicated in patients with the following conditions:

- Acute cervicitis
- Pregnancy
- Cervical or Uterine malignancy
- Acute pelvic inflammatory disease
- Unaddressed adnexal pathology

While fluids must always be monitored during use, exercise extreme caution and very close fluid monitoring in patients with severe cardiopulmonary disease.

Karl Storz Bipolar Electrodes must not be used for interventions on the CNS.

KARL STORZ – ENDOSKOPE

Predicate Devices: The KSEA Bipolar Electrode is substantially equivalent to the predicate Bipolar Electrotome (K061541) and GYNECARE VERSAPOINT Bipolar Electrosurgery System (K111751)

Technological Characteristics:

Bipolar Electrotome

The subject KSEA Electrode is substantially equivalent to Bipolar Electrotome (K061541) with the same features, dimensions, body contact and insulation materials, and intended use. The only difference between the subject electrodes and the predicate electrodes is that the subject electrodes are indicated for gynecological procedures whereas the predicate device is indicated for urological procedures.

The Safety and performance equivalence are demonstrated by the testing of IEC 60601-1, IEC 60601-2-2 and IEC 60601-2-18.

GYNECARE VERSAPOINT II Bipolar Electrosurgery System

There is no significant technological difference between the predicate and subject device. Both devices are bipolar and have the same intended use. Both uses a generator for the source of energy. The minor differences in material do not affect the safety and effectiveness of the devices. The performance equivalence of the devices can be demonstrated by the passing criteria of the IEC 60601-2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories. Both the predicate and subject device have undergone and passed IEC 60601-2-2 to demonstrate the equivalence to the essential performance of the HF equipment and accessories. For additional safety requirements equivalence, both subject and predicate devices have also undergone and pass IEC 60601-1 and IEC 60601-2-18.

Performance and Safety Testing:

Two bench studies, Comparison of Gas Product and Visual Depth of Thermal Penetration, are used to demonstrate the performance substantial equivalence of the subject and predicate devices. In addition, both predicate and subject devices have undergone sterilization validation, biocompatibility testing and non-clinical conformance standard testing: IEC 60601-1, IEC 60601-2-2 and IEC 60601-2-18.

KARL STORZ—ENDOSKOPE

Conclusions:

The test results presented in the testing report of abovementioned testing have demonstrated the substantial equivalence in both safety and performance of the predicate and subject device. Thus, the minor differences between the predicate and subject devices do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 26, 2013

KARL STORZ Endoscopy-America, Inc.
% Ms. Winkie Wong
Regulatory Affairs Specialist
2151 E. Grand Avenue
EL SEGUNDO CA 90245

Re: K122983
Trade/Device Name: Karl Storz Bipolar Electrode
Regulation Number: 21 CFR§ 884.4150
Regulation Name: Bipolar endoscopic coagulator-cutter and accessories
Regulatory Class: II
Product Code: HIN
Dated: May 22, 2013
Received: May 24, 2013

Dear Ms. Wong:

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" (21CFR 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,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

KARL STORZ—ENDOSKOPE

510(k) Number (if known): K122983

Device Name: Karl Storz Bipolar Electrode

Indications for Use: The Karl Storz Bipolar Electrode is intended for use in tissue cutting, removal and desiccation as required or encountered in gynecologic hysteroscopic electrosurgical procedures for the treatment of intrauterine myomas, polyps, adhesions and septa, and benign conditions requiring endometrial ablation. Procedures include:

- Excision of intrauterine myomas
- Excision of intrauterine polyps
- Lysis of intrauterine adhesions
- Incision of uterine septa
- Endometrial ablation

Prescription Use __x__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S