JAN 8 1999

K983589

page 1 of 1

## 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) 558-1500

**Contact:**

Kevin Kennan
Regulatory Affairs Specialist

**Device Identification:**

Common Name:
Monopolar Electrodes

Trade Name: (optional)
KSEA Monopolar Vaporization Electrodes

**Indication:** The KSEA Monopolar Vaporization Electrodes are indicated for use by qualified surgeons during Ob/Gyn hysteroscopic surgical procedures including:

- abnormal uterine bleeding,
- infertility,
- transuterine resection of fibroids,
- endometrial ablation,
- resectoscopic management of Mullerian fusion defects,
- resectoscopic management of intrauterine lesions, and
- resectoscopic management of intractable uterine bleeding.

**Device Description:** The KSEA Monopolar Vaporization Electrodes are manual single-use sterile surgical devices. The body contact materials are surgical grade stainless steel, tungsten, and a copper/nickel alloy. The Monopolar Vaporization Electrodes are insulated with commonly used materials.

**Substantial Equivalence:** The KSEA Monopolar Vaporization Electrodes 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 KSEA Monopolar Vaporization Electrodes 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.

Signed: _____

Kevin Kennan
Senior Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 8 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kevin A. Kennan
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe
Culver City, CA 90230

Re: K983569
Spike 5mm 27050 VG, Spike 3mm 27050 VK,
Roller 5mm 27050 RG, Roller 3mm 27050 RK,
Roller Cutting 27050 KG, VAPOR Cutting 27050 SG,
VAPOR CUT 27050 WG
Dated: October 7, 1998
Received: October 13, 1998
Regulatory Class: II
21 CFR 884.1690/Procode: 85HIH
21CFR 884.4160/Procode: 85KNF

Dear Mr. Kennan

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Monopolar Vaporization Electrodes

Indications for Use: These instruments are intended for use by qualified surgeons during Ob/Gyn hysteroscopic surgical procedures including:

- abnormal uterine bleeding,
- infertility,
- transuterine resection of fibroids,
- endometrial ablation,
- resectoscopic management of Mullerian fusion defects,
- resectoscopic management of intrauterine lesions, and
- resectoscopic management of intractable uterine bleeding.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983569

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

(Optional Format 1-2-96)