Karl Storz
Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, California 90230-7600
Phone (310) 558-1500
Toll Free 800 421 0671
Fax 310 410 1552

K972497

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 are accurate to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, California 90230
(310) 558-1500

Contact: Marlena Allen Piercy, Ph.D.
Senior Clinical Affairs Specialist

Device Identification: Common Name:
Electrosurgical Coagulating Electrodes
Electrosurgical Needle Electrodes

Trade Name (optional):
KSEA Monopolar Coagulating Electrodes
KSEA Monopolar Coagulating Needle Electrode

Indication: The KSEA Monopolar Coagulating and Needle Electrodes are designed to be used by qualified surgeons and physicians to cut, coagulate, and/or fulgurate tissue via high-frequency electrical current wave forms, during endoscopic general and plastic surgical procedures.

Device Description: The KSEA Monopolar Coagulating and Needle Electrodes are reusable surgical devices. The body-contact portions of the electrodes are composed of AISI series 420 surgical-grade stainless steel. The shafts are composed of AISI series 303 and 304 surgical-grade stainless steel, and are insulated with polytetrafluoroethylene (PTFE).

Substantial Equivalence: The KSEA Monopolar Coagulating and Needle Electrodes are substantially equivalent to the predicate devices since the basic designs and intended uses are the same. The minor difference between the KSEA Monopolar Coagulating and Needle Electrodes and the predicate devices raise no new issues of safety and effectiveness, as the design differences have no effect on the performance, function, or intended uses of the devices.

Signed: Marlena Allen Piercy
Marlena Allen Piercy, Ph.D.
Senior Clinical Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1997

Marlena Allen Piercy, Ph.D.
Senior Clinical Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, California 92030-7600

Re: K972497
Trade Name: Karl Storz Monopolar Coagulating Electrodes and Karl Storz Monopolar Coagulating Needle Electrodes
Regulatory Class: II
Product Code: GEI
Dated: July 2, 1997
Received: July 3, 1997

Dear Dr. Piercy:

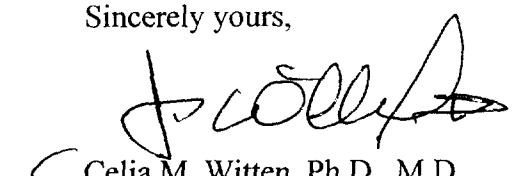
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 devices in the Federal Register. Please note: this response to your premarket notification submissions 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

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

If you desire specific advice for your devices 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) 594-4595. Additionally, for questions on the promotion and advertising of your devices, 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/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Karl Storz
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600 Corporate Pointe
Culver City, California 90230-7600
Phone 310 558 1500
Toll Free 800 421 0812
Fax 310 410 5527

K972497

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

Device Name: Monopolar Coagulating Electrodes for General and Plastic Surgery

Indications for Use:

The Monopolar Coagulating Electrodes are indicated for use in cutting, coagulating, and/or fulgurating tissue during endoscopic general and plastic electrosurgical 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 General Restorative Devices
510(k) Number K972497