AUG - 3 2001

K010345

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:

James A. Lee
Regulatory Affairs Specialist

Device Identification:

Common Name:
Bipolar Forceps

Trade Name: (optional)
The KSEA MANHES Take-apart® Bipolar Coagulating Forceps

Indication: The KSEA MANHES Take-apart® Bipolar Coagulating Forceps are intended for use by qualified surgeons to manipulate and coagulate tissue via a high frequency electrical current waveform during various spinal surgical procedures.

Device Description: The KSEA MANHES Take-apart® Bipolar Coagulating Forceps are manual surgical devices. The body contact materials are surgical grade stainless steel. The KSEA MANHES Take-apart® Bipolar Coagulating Forceps are insulated with commonly used materials.

Substantial Equivalence: The KSEA MANHES Take-apart® Bipolar Coagulating Forceps are substantially equivalent to the predicate devices since the basic design, dimensions, stainless steel, insulator materials and general intended uses are similar. The minor differences between the KSEA MANHES Take-apart® Bipolar Coagulating Forceps and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed: _____
James A. Lee, Ph.D.
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2001

Mr. James A. Lee
Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc
600 Corporate Pointe Drive
Culver City, California 90230

Re: K010345
Trade/Device Name: KSEA MANHES Take-apart® Bipolar Coagulating Forceps
Regulation Number: 888.1100
Regulatory Class: II
Product Code: HRX
Dated: April 26, 2001
Received: May 7, 2001

Dear Mr. Lee:

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) 594-4659. 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" (21CFR 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,

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

Enclosure

510(k) Number (if known): Not yet assigned. K010345

Device Name: KSEA MANHES Take-apart® Bipolar Coagulating Forceps

Indications for Use: The KSEA MANHES Take-apart® Bipolar Coagulating Forceps are intended for use by qualified surgeons to manipulate and coagulate tissue via a high frequency electrical current waveform during various spinal surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010345