K 981233

pg 1 of 2

JUN 15 1998

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
Senior Regulatory Affairs Specialist

Device Identification:

Common Name:
Pneumatic Lithotriptor

Trade Name: (optional)
Karl Storz Calcusplit

Indication: The Karl Storz Calcusplit system is intended for use by qualified surgeons and provides for the pneumatic fragmentation of renal and lower ureteral calculi.

Predicate: EMS Swiss Lithoclast Lithotriptor

Device Description: The Karl Storz Calcusplit is a pneumatic lithotriptor designed for the pneumatic fragmentation of urinary calculi. The Calcusplit system uses pneumatic energy converted to mechanical energy to disintegrate calculi. The force of the mechanical energy provided by this device is sufficient to fragment calculi of most sizes and composition.

Substantial Equivalence: The Karl Storz Calcusplit is substantially equivalent to the EMS Swiss Lithoclast currently marketed by Boston Scientific Corporation (K951531 and K963285); the Karl Storz Calcusplit has the same intended use as the predicate Swiss Lithoclast and has the same technological characteristics as the predicate Swiss Lithoclast. Both the Calcusplit and the Lithoclast systems use compressed air and direct contact, rigid probes to fragment urinary tract stones under direct vision endoscopic control.

Bench testing of probe endurance and tissue effects was conducted and demonstrated that the safety and effectiveness of the Calcusplit system was no worse than the safety and efficacy for the EMS Swiss Lithoclast Lithotriptor. An unmasked and self-controlled multi-center

clinical trial of the Calcusplit system for fragmentation of lower ureter and renal stones was also conducted. The study demonstrated that the safety and effectiveness of the Calcusplit system in fragmenting lower ureter (ureteroscopic approach) and renal stones (percutaneous approach) was no worse than the safety and efficacy for the EMS Swiss Lithoclast Lithotriptor.

Signed: _____

Kevin Kennan
Senior Regulatory Affairs Specialist

Date: March 31, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 1998

Mr. Kevin Kennan
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy
600 Corporate Pointe
Culver City, CA 90230-7600

Re: K981233
Calcusplit Lithotriptor and Accessories
Dated: March 31, 1998
Received: April 3, 1998
Regulatory Class: III
21 CFR 876.4480/Procode: 78 FFK

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K981233

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

Device Name: Calcusplit Lithotriptor

Indications for Use: These instruments are intended for use by qualified surgeons and provide for the intracorporeal fragmentation of lower ureter and renal calculi.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter R Rolling

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K981233

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

(Optional Format 1-2-96)