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**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 Lithotripter

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 bladder calculi.

**Predicate:** EMS Swiss Lithoclast Lithotripter

**Device Description:** The Karl Storz Calcusplit is a pneumatic lithotripter 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.

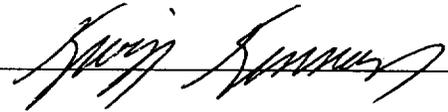
**Substantial Equivalence:** The Karl Storz Calcusplit is substantially equivalent to the EMS Swiss Lithoclast currently marketed by Boston Scientific Corporation (K951531 and K963285); the Karl Storz Calcusplit has the same intended use as the predicate Swiss Lithoclast and has the same technological 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

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for the EMS Swiss Lithoclast Lithotripter. A literature search demonstrated that Pneumatic Lithotripsy (PL) is a safe and effective means of fragmenting urinary stones.

Signed:



Kevin Kennan  
Senior Regulatory Affairs Specialist

Date: June 18, 1999



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K992114  
Calculusplit Lithotripter  
Dated: June 18, 1999  
Received: June 22, 1999  
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 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):

K 992114

Device Name: Calcusplit Lithotripter

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

(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)

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

(Optional Format 1-2-96)

David A. Segman  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

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