OCT 1 6 2001

K012482

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 and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe
Culver City, CA 90230
(310) 338-8100

Contact: Jennifer S. Portugal
Clinical Affairs Specialist

Device Identification:

Common Name
Lithotripter

Trade Name
The Storz Modulith® Lithotripter Model SLK with Multiview option

Indication: The Storz Modulith® Lithotripter Model SLK with Multiview option is intended for noninvasive fragmentation of urinary calculi in the kidney and upper ureter.

Device Description: The Storz Modulith® Lithotripter Model SLK with Multiview option is an extracorporeal pressure wave lithotripter. The Multiview option facilitates the additional display of up to two imaging systems on the Lithotrack® monitor.

Substantial Equivalence: The Storz Modulith® Lithotripter Model SLK with Multiview option for lithotripsy is substantially equivalent to the predicate device since the basic features and intended use are identical, and the design is similar. The minor differences between the Storz Modulith® Lithotripter Model SLK with Multiview option and the predicate device raises no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed: _____
Jennifer S. Portugal
Clinical Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 6 2001

Ms. Jennifer S. Portugal
Clinical Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe, 5th Floor
CULVER CITY CA 90230-7600

Re: K012482
Trade/Device Name: Storz Modulith® Lithotripter Model SLK with Multiview option
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: 78 LNS
Dated: July 31, 2001
Received: August 2, 2001

Dear Ms. Portugal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012482 ~~Not yet assigned~~

Device Name: Storz Modulith® Lithotripter Model SLK with Multiview option

Indications for Use: The Storz Modulith® Lithotripter Model SLK with Multiview option is indicated for use in the noninvasive fragmentation of kidney and upper ureteral calculi.

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

Concurrence of CDRH, Office of ~~Device~~ Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, ~~Abdominal,~~
and Radiological Devices
510(k) Number K012482

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

(Optional Format 1-2-96)