K070579

AUG 30 2007

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:

Paul S. Lee
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Device Identification:

Common Name: Extracorporeal Shock Wave Lithotripter

Trade Name: Storz SLX-F2 *Storm Touch®*

Indication:

The Storz SLX-F2 *Storm Touch®* software allows remote control / display communication between *Storz Communication Buss®* (SCB) network computer and *SLX-F2 System®* via a graphic user interface with a touch panel LCD screen. The SLX-F2 *Storm Touch®* interface communication software permits additional remote control and adjustment of the third party device through *Storm Touch®*.

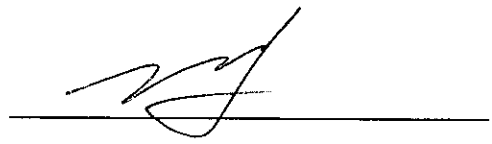
Device Description:

The new *Storm Touch®* software allows remote control / display / communication between the SCB system and SLX-F2 System via a graphic user interface with a touch panel LCD screen. The main function of the *Storm Touch®* graphical user interface is to support the doctor by displaying SLX-F2 control panel System including its x-ray parameters during lithotripsy treatment or surgery. This SCB *Storm Touch®* communication software does not add any new clinical function to the SLX-F2 and third party devices. *Storm Touch®* has the same graphic user interface principle as our original SCB graphic interface software.

Storm Touch® is installed as an optional software in the SCB computer which is located in the OR suite. SLX –F2 connects to the SCB system by a specific Buss Connectors in the SCB computer with a designated cable.

The SCB *Storm Touch®* interface communication software also permits additional remote control and adjustment of the third party device. All third party devices that are connected to the SCB *Storm Touch®* may still be controlled by the original device overwriting the SCB control. In case the additional remote control is not required, control of the device still remains with the device itself. The SCB *Storm Touch®* software allows additional optional control / communication of the third party device with the SCB.

Substantial Equivalence: The Storz Medical SLX-F2 *Storm Touch®* is substantially equivalent to predicate devices since the basic technology and design are similar. The intended usage is similar to predicate devices and raise no new issues of safety and effectiveness. The minor differences between the Storz Medical Storz SLX-F2 *Storm Touch®* and predicate devices have no effect on the performance, function or intended use of the devices.

Signature: 

Paul Lee
Senior Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 30 2007

Mr. Paul S. Lee
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe Drive
CULVER CITY CA 90230

Re: K070579
Trade/Device Name: Storz SLX-F2 Storm Touch®
Regulation Number: 21 CFR §876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: July 27, 2007
Received: July 31, 2007

Dear Mr. Lee:

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 (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 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 Section 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:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

K070579

INDICATIONS FOR USE

510(k) Number (if known): K070579

Device Name:

Storz SLX-F2 *Storm Touch®*

Indications for Use:

The Storz SLX-F2 *Storm Touch®* software allows remote control / display communication between *Storz Communication Buss®* (SCB) network computer and *SLX-F2 System®* via a graphic user interface with a touch panel LCD screen. The SLX-F2 *Storm Touch®* interface communication software permits additional remote control and adjustment of the third party device through *Storm Touch®*.

Prescription Use: _____ OR Over-The-Counter Use: _____
(Per 21 CFR 801.Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

JWhang

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070579