K093603

STORZ
Karl Storz Endoscopy

MAR 18 2010

510(k) Summary of Safety and Efficacy

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.

Date Prepared	3-05-2010
Applicant:	Karl Storz Endoscopy of America, Inc. 2151 Grand Ave El Segundo, CA 90245
Contact:	Leigh Spotten Regulatory Affairs Manager (424) 218-8738 Email: lspotten@ksea.com
Device Identification / Classification	StorM-Base 2.0 System, Image Processing, Radiological 892.2050 Class II
Indication:	StorM-Base 2.0 is intended to be used by physicians and other qualified medical personnel for the documentation, communication, display, printing and storage of medical diagnostic data in the field of Lithotripsy. When installed with a Storm-Touch system, it is also an image archiving system based on the DICOM standard capable of capturing and annotating lithotripsy procedures for documentation purposes. Images imported and distributed by StorM-Base 2.0 are for viewing and reference purposes only and are not intended for primary diagnosis.
Device Description:	The Strorz StorM-Base 2.0 is a Windows XP based software application that stores patient data, examination results including the number, type and location of stones, treatment images and data. The application may be installed on a standalone PC or on the StroM-Touch MODULITH Lithotripter (K070579). When installed on the StroM-Touch MODULITH Lithotripter, the system can acquire the images and treatment data directly from the lithotripter via an import function

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	and be networked to the Storz Controller Buss.
Predicate Devices	The Storz StorM-Base 2.0 is substantially equivalent to the Storz AIDA with DICOM and HL7 interface (K043324)
Technical Characteristics	The proposed device and the predicate are Windows® based software communication systems, deployed on a standalone PC or networked, intended to be used by Health Professionals, are accessories to the hospital information system (HIS), store patient information, comply with the HL7 and DICOM standards, require password login and authorization, store and archive data locally, import and distribute images. The proposed device and the predicate do not manipulate original PACS or HIS data and the stored images are not intended for diagnostic use.
Summary of Non-Clinical Testing	The Storz StorM-Base 2.0 has been developed in compliance with software verification and validation methods. Appropriate risk control measures have been identified and implemented through a risk management process that meets the requirements of ISO 14971. Verification and validation testing has been performed to ensure that requirements have been properly implemented. The device has been verified to be in compliance with the DICOM standard.
Substantial Equivalence:	The basic technology, design and intended use is similar to predicate device and raise no new issues of safety and effectiveness. The minor differences between the StorM-Base 2.0 and predicate devices have no effect on the performance, function or intended use of the devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Leigh Spotten
Regulatory Affairs Manager
Karl Storz Endoscopy-America, Inc.
2151 E, Grand Avenue
EL SEGUNDO CA 90245

MAR 18 2010

Re: K093603
Trade/Device Name: StorM-Base 2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 5, 2010
Received: March 8, 2010

Dear Ms. Spotten:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication For Use

510(k) Number (if known): K093603

Device Name: StorM-Base 2.0

Indications For Use:
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Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 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)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K093603