K043324

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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) 338-8100

Establishment Number: 2020550

Contact: Paul S. Lee
Senior Regulatory Affairs Specialist
Telephone +1-310-410-2769
Telecopier +1-310-410-5519

Device Identification / Classification:

- Trade Name: AIDA/DICOM/HL7
- Classification Name: Picture Archiving and Communications System
- Classification Panel: Reproductive, Abdominal, Radiological Devices
- CFR Section 21CFR892.2050
- Device Class: Class II
- Product Code: LIZ

Indication:

This software is intended for use by qualified personnel in the Operating Room and Nurses Station. The Advanced Image and Data Archiving System (AIDA) is a Windows® based still/video image capturing, archiving, documentation system and recording of audio sequences and patient data during a procedure. It allows capture and annotation of the

surgical procedure for documentation purposes. Images captured and distributed by AIDA are for viewing and reference purposes and are not intended for primary diagnosis.

It is also a Windows® based solution to communicate with other picture archival communication systems (PACS) using DICOM and with Hospital Information Systems (HIS) using the HL7 standard. Also as a part of the AIDA system the Storz Application Manager software (SAM) enables the selection and integrations of AIDA functions with various compatible applications, such as Karl Storz's Storz Communication Bus (SCB) or other third party image capturing devices.

Device Description:

The Karl Storz AIDA/DICOM/HL7 is an image capturing device with DICOM viewer which communicates with the Hospital Information System via HL7 protocol.

Substantial Equivalence:

The Karl Storz AIDA/DICOM/HL7 is substantially equivalent to the predicate device (SIENET MagicWeb and Magic Link I: K973131) since the basic features and intended uses are the same. The minor differences between the Karl Storz AIDA/DICOM/HL7 and the predicate device raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

General Safety and Effectiveness Concerns:

Built in screen prompts, alarms, error messages and warnings ensure safe and effective use of the AIDA/DICOM/HL7 software. Risk management is ensured *via* risk analyses, which are used to identify potential hazards. These hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical and radiation hazards, KSEA adheres to recognized and established industrial practice and standards.

Signed: _____

Paul Lee
Senior Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2005

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

Re: K043324
Trade/Device Name: AIDA with DICOM and HL7 interface
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Product Codes: KOG and FET
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Product Code: LLZ
Regulatory Class: II
Dated: March 1, 2005
Received: March 16, 2005

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (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

Indication for Use Form

510(k) Number (if known): ~~Not yet assigned~~ K043324

Device Name: AIDA with DICOM and HL7 interface

Indications for Use:

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Prescription Use: ✓ AND/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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043324

Confidential