K080852

MAR 3 0 2009

KARL STORZ ENDOSCOPY

510(k) SUMMARY

Sponsor/Submitter:	Karl Storz Endoscopy-America, Inc. 600 Corporate Pointe Culver City, CA 90230-7600 Phone: (310) 338-8100 Fax: (310) 410-5519
Contact Person:	Crystal Dizol Regulatory Affairs Specialist Email: cdizol@ksea.com
Date of Submission:	March 25, 2008
Device Trade Name:	KSEA Electronic CO_2 ENDOFLATOR LC
Common Name:	Laparoscopic insufflator
Classification Name:	Laparoscopic insufflator
Regulation Number:	21 CFR 884.1730
Product Code:	HIF
Predicate Device(s):	KSEA CO2 ENDOFLATOR (K963423) Karl Storz Model 264305-20 Electronic ENDOFLATOR (K962863)
Device Description:	The KSEA Electronic CO_2 ENDOFLATOR LC is an insufflation device for universal application in laparoscopic examinations and operations.
Indications for Use:	The KSEA Electronic CO_2 ENDOFLATOR LC provides CO_2 gas distention of the abdomen for the diagnostic and/or operative laparoscopy. See the instruction manual for your laparoscope for special indications for use.
Technological Characteristics:	The KSEA Electronic CO_2 ENDOFLATOR LC is an electronic CO_2 gas insufflator. The device is intended to be used with a central gas supply line to achieve pressures from 0-30 mmHg and flow rates of 0-30 L/min.
Summary of Substantial Equivalence:	The KSEA Electronic CO_2 ENDOFLATOR LC is substantially equivalent to the predicate devices since the basic features, design, and intended uses are similar. The minor differences between the KSEA Electronic CO_2 ENDOFLATOR LC and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no affect on the performance, function, or intended use of the devices. For a comparison between the KSEA Electronic CO_2 ENDOFLATOR LC and the predicate devices, refer to the attached substantial equivalence chart.

KARL STORZ ENDOSCOPY

SUBSTANTIAL EQUIVALENCE TABLE FOR KSEA ELECTRONIC CO_2 ENDOFLATOR LC

Manufacturer	Max Flow Rate	Max Output Pressure	Gas Type	Display Type	Safety Features	Intended Use
KSEA: Electronic CO_2 ENDOFLATOR LC	**30 L/min**	**30 mmHg**	**CO_2**	**Digital**	**Self-test procedure, overpressure blow-off valve, audible alarms**	**The KSEA Electronic CO_2 ENDOFLATOR LC provides CO_2 gas distention of the abdomen (pneumoperitoneum) for diagnostic or operative laparoscopy. See the instruction manual for your laparoscope for special indications for use.**
KSEA: Model 264305-20 Electronic Endoflator (K962863)	20 L/min	30 mmHg	CO_2	Digital	Self-test procedure, overpressure blow-off valve, audible alarms	The Electronic Endoflator provides CO_2 gas distension of the abdomen for diagnostic and/or operative laparoscopy. Please consult the instruction manual for your laparoscope for specific indications for use.
KSEA: Model 264320-20 Thermoflator (K955073)	30 L/min	30 mmHg	CO_2	Digital	Self-test procedure, overpressure blow-off valve, audible alarms	This device is designed to carefully deliver large flow rates for rapid insufflation, and monitor the amounts of CO_2 gas needed to establish and maintain proper distention of the peritoneal cavity during Ob/Gyn laparoscopic surgical and diagnostic procedures.

K080852

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2009

Ms. Crystal K. Dizol
Regulatory Affairs Specialist
KARL STORZ Endoscopy-America, Inc.
2151 E. Grand Avenue
EL SEGUNDO CA 90245

Re: K080852
Trade/Device Name: KSEA Electronic CO_2 ENDOFLATOR LC
Regulation Number: 21 CFR §884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF
Dated: March 6, 2009
Received: March 9, 2009

Dear Ms. Dizol:

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 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 os 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, 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.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K080852

Device Name: KSEA Electronic CO_2 ENDOFLATOR LC

Indications for Use: The KSEA Electronic CO_2 ENDOFLATOR LC provides CO_2 gas distention of the abdomen (pneumoperitoneum) for diagnostic or operative laparoscopy. See the instruction manual for your laparoscope for special indications for use.

Prescription Use: ✓ AND/OR Over-The-Counter Use: _____
(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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080852