

No 8 2925

DEC 18 2008

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) 558-1500

Contact: Monika Campbell
Senior Regulatory Affairs Specialist


Device Identification: **Common Name:**
Light Source

Trade Name: (optional)
Xenon-100 SCB Light Source

Indications for Use: The KSEA Xenon-100 SCB Light Source is intended for use in combination with Karl Storz video-endoscopes for gastro-enterology or with Karl Storz endoscopes for general purpose endoscopy by qualified surgeons and is equipped with the SCB-feature which provides remote control of the light source for central operation, central display, automatic initial setting and interlocking operation to the Karl Storz SCB Control Computer (Karl Storz Communication Bus), to relay functions and controls on the SCB monitor.

Device Description: The Karl Xenon-100 SCB is a Light Source unit for Karl Storz video gastro-endoscopes.

Substantial Equivalence: The Karl Storz Xenon-100 SCB Light Source is substantially equivalent to the predicate device since the basic features and intended uses are the same. The minor differences between the Karl Storz Xenon-100 SCB Light Source and the predicate device raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or general intended use of these devices.

Signed: 

Monika Campbell
Senior Regulatory Affairs Specialist



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2008

Ms. Monika Campbell
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe, 5th Floor
CULVER CITY CA 90230-7600

Re: K082925

Trade/Device Name: Xenon-100 SCB Light Source
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCT
Dated: September 30, 2008
Received: October 1, 2008

Dear Ms. Campbell:

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.

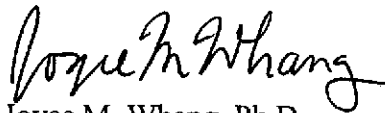
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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). 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 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,



Joyce M. Whang, Ph.D.
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): K082925

Device Name: Xenon-100 SCB Light Source

Indications for Use: The KSEA Xenon-100 SCB Light Source is intended for use in combination with Karl Storz video-endoscopes for gastro-enterology or with Karl Storz endoscopes for general purpose endoscopy by qualified surgeons and is equipped with the SCB-feature which provides remote control of the light source for central operation, central display, automatic initial setting and interlocking operation to the Karl Storz SCB Control Computer (Karl Storz Communication Bus), to relay functions and controls on the SCB monitor.

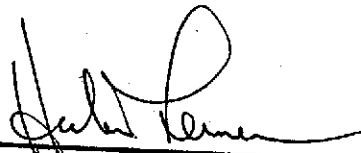
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K082925

Page X of X

(Posted November 13, 2003)