

DEC 15 1999

**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:** Kevin Kennan  
Regulatory Affairs Specialist

**Device Identification:** **Common Name:**  
Neuroendoscope

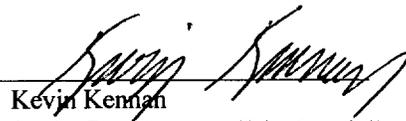
**Trade Name:** (optional)  
Karl Storz Direct Coupled Interface (DCI) Endoscope

**Indication:** The KSEA DCI Endoscope is indicated for viewing the ventricles of the brain and performing diagnostic and therapeutic procedures.

**Device Description:** The KSEA DCI Endoscope is comprised of a rigid, panoramic telescope which utilizes rod lens technology. The body contact portions of the KSEA DCI Endoscope are composed of surgical grade stainless steel, which is commonly used in medical devices for a wide range of applications and has a long history of biocompatibility for human use.

**Substantial Equivalence:** The KSEA DCI Endoscope is substantially equivalent to the predicate devices since the basic features, design and intended uses are the same. The minor differences between the KSEA DCI Endoscope 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.

Signed: \_\_\_\_\_

  
Kevin Kennan  
Senior Regulatory Affairs Specialist



DEC 15 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Kevin A. Kennan  
Senior Regulatory Affairs Specialist  
Karl Storz Endoscopy-America, Inc.  
600 Corporate Pointe  
Culver City, California 90230

Re: K993539  
Trade Name: Direct Coupled Interface (DCI) Endoscope  
Regulatory Class: II  
Product Code: GWG  
Dated: October 18, 1999  
Received: October 19, 1999

Dear Mr. Kennan:

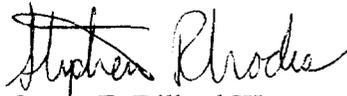
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
for James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K993539

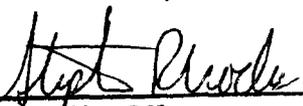
510(k) Number (if known):

Device Name: Karl Storz Direct Coupled Interface (DCI) Endoscope

Indications for Use: These instruments are manually operated surgical devices intended for use by qualified surgeons for viewing the ventricles of the brain and performing diagnostic and therapeutic procedures.

(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 General Restorative Devices  
510(k) Number K993539

Prescription Use:  OR Over-The-Counter Use: \_\_\_\_\_  
(Per 21 CFR 801.109)

(Optional Format 1-2-96)