

MAY 8 1998

K980694

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

P191

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
Senior Regulatory Affairs Specialist

Device Identification: **Common Name:**
Trocar and Cannula

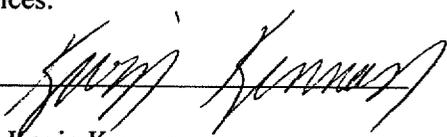
Trade Name: (optional)
Karl Storz Plastic Trocar

Indication: The KSEA Plastic Trocars are intended for making incisions into the patient's body to allow insertion of endoscopes and endoscopic accessories during Ob/Gyn laparoscopic procedures.

Device Description: The Karl Storz Plastic Trocars are manually operated surgical devices. The body contact portions of the KSEA Plastic Trocars are composed of surgical grade stainless steel and PEEK which are commonly used in medical devices for a wide range of applications and have a long history of biocompatibility for human use.

Substantial Equivalence: The Karl Storz Plastic Trocars are substantially equivalent to the predicate devices since the basic features and intended uses are similar. The minor differences between the Karl Storz Plastic Trocars and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed: _____



Kevin Kennan
Senior Regulatory Affairs Specialist



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 8 1998

Mr. Kevin Kennan
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe
Culver City, CA 90230-7600

Re: K980694
Plastic Trocars with Silicone Leaflet Valve
Dated: February 20, 1998
Received: February 23, 1998
Regulatory Class: II
21 CFR 884.1720/Procode: 85 HET

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 (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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

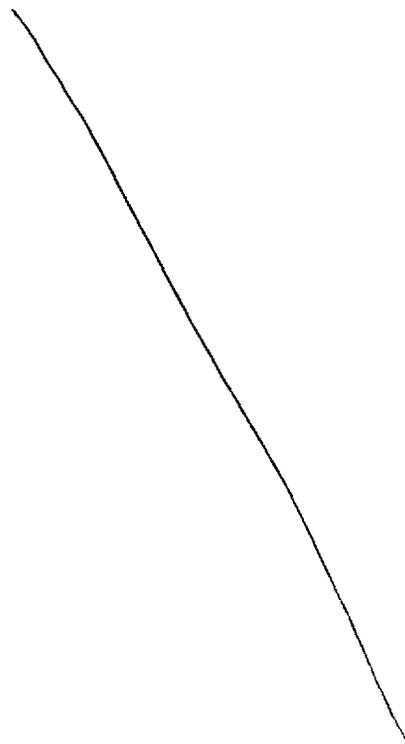
Enclosure

K980694

510(k) Number (if known): Not Yet Assigned

Device Name: KSEA Plastic Trocars

Indications for Use: These instruments are manually operated surgical devices intended for making incisions into the patient's body to allow insertion of endoscopes and endoscopic accessories during Ob/Gyn laparoscopic procedures.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Sathiyaj
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980694

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

(Optional Format 1-2-96)

000003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Patrick Janin
General Manager
Future Medical Systems, Inc.
504 McCormick Drive, Suite T
Glen Burnie, MD 21061

Re: K980808
ENDO FMS® UROLOGY
(Fluid Management System)
Dated: March 30, 1998
Received: April 1, 1998
Unclassified/Procode: 78 LJE
Regulatory Class: II
21 CFR §876.1500/Procode: 78 FDC

Dear Mr. Janin:

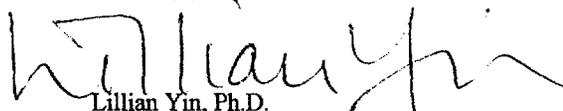
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements, 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.

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Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K980808

Device Name: ENDO FMS® UROLOGY

Indications For Use:

The ENDO FMS® UROLOGY is a fluid management system used to maintain adequate irrigation pressure and flow in endoscopic Urology procedures, including all endoscopic procedures in the Kidney, Ureter/Urethra , Bladder and Prostate.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Rathling /
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K980808

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)