STORZ
Karl Storz Endoscopy

AUG - 9 1995

K 952473

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 CRF 807.92. All data included in this documents are accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe
Culver City, CA 90230
(310) 558-1500

Contact: Betty M. Johnson
Manager, Regulatory Affairs

Device Identification:

Common Name
Powder Blower

Trade Name
KSEA Powder Blower for Thoracoscopy

Indication: Treatment of malignant pleural effusion by insufflation of medical grade talc following drainage of pleural fluid.

Device Description: The KSEA powder blower is comprised of a number of individual components: a glass bottle, an insufflation cannula, and an insufflation bulb. The body contact materials in the KSEA powder blower are commonly used in medical devices for a wide range of applications and have long histories of biocompatability for human use.

Substantial Equivalence: The KSEA powder blower is substantially equivalent to the predicate devices since the basic features, design and intended uses are the same. The minor differences between the KSEA powder blower and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function or intended use of the devices.

Signed: Betty M. Johnson

Betty M. Johnson
Manager, Regulatory Affairs

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 9 1995

Ms. Betty M. Johnson
Manager, Regulatory Affairs
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, California 90230-7600

Re: K952443
Trade Name: Karl Storz Powder Blower for Thoracoscopy
Regulatory Class: II
Product Code: GCJ
Dated: May 23, 1995
Received: May 25, 1995

Dear Ms. Johnson:

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 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), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the device as described below. 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

Our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for thoracoscopically assisted intrathoracic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

As you are aware, there are concerns relating to the fact that no drug is currently labeled for administration via a thoracoscopically assisted intrathoracic delivery device. The Agency currently is evaluating this public health concern regarding the safety and effectiveness of this route of administration of drugs, and in the near future will inform manufacturers of certain additional steps the Agency believes are necessary to address this concern.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion or advertising, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Alan C Jones for

Kimber C. Richter, M.D.
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health