



Storz
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K953550

23 1995

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 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
Orthopedic Insufflator

Trade Name
KSEA Model 284120 20 CO₂ Arthroflator

Indication: The KSEA Model 284120 20 CO₂ Arthroflator is designed to facilitate the use of arthroscopes by distending the area surrounding a joint with CO₂ gas during arthroscopic surgical and diagnostic procedures.

Device Description: The KSEA Model 284120 20 CO₂ Arthroflator for arthroscopy is a mechanical insufflator system with a maximum gas flow rate of 1.5 liters per minute. The insufflation pressure is continuously adjustable between 50 and 100 mmHg. The safety features include high and low pressure blow-off valves.

Substantial Equivalence: The KSEA Model 284120 20 CO₂ Arthroflator system for arthroscopy is substantially equivalent to the predicate devices since the basic features, design and intended uses are similar. The minor differences between the KSEA Arthroflator 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: Betty M. Johnson
Betty M. Johnson
Manager, Regulatory Affairs



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

AUG 23 1995

Renate A. MacLaren, Ph.D.
Regulatory Affairs Specialist
Karl Storz Endoscopy America, Inc.
600 Corporate Pointe
Culver City, California 90230-7600

Re: K953550
KSEA Model 28120 20 CO₂ Arthroflator
Orthopedic Insufflator
Regulatory Class: II
Product Code: HRX
Dated: July 27, 1995
Received: July 28, 1995

Dear Dr. MacLaren:

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). 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, 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 immediately. 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 its toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



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