K983220

JUN 4 1999

stryker®
ENDOSCOPY 2590 Walsh Ave. Santa Clara, CA 95051

SUMMARY SAFETY AND EFFICACY

Device Name

Current Classification Name(s):	Esophageal Dilator; 21 CFR 876.5365: Gastroenterology-Urology Devices.
Common and Usual Name:	Stryker Esophageal Kit or E-kit
Proprietary Name:	Stryker InfraVision™ Esophageal Kit

Device Sponsor

Stryker Endoscopy
2590 Walsh Ave.
Santa Clara, CA 95051

This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The Stryker InfraVision™ Esophageal Kit illumination source will comply with 21 CFR 1040.10 Performance Standards for Lasers and voluntarily comply with UL 544 and/or UL 2601 Standard for Medical and Dental Equipment..

The Stryker InfraVision™ Esophageal Kit will be constructed of materials which are of the same manufacturing process, chemical composition, body contact and sterilization methods as currently marketed and approved medical devices and are safe, effective, and durable for their intended purposes.

The Stryker InfraVision™ Esophageal Kit is equivalent in safety and effectiveness to a variety of devices currently marketed (Gabriel InfraVision™ Esophageal Kit - K960173; Bard Balloon Dilatation System - K863437; Sherwood Argyle Salem Sump Tube - K810156; BioEnterics EndoLumina Illuminated Bougie - K934048) which are used in the applications noted above.

This device does not raise new issues when compared to its predicate devices or uses. Therefore, it is considered substantially equivalent to those devices.

Sean Cahill
Design Engineer

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 4 1999

Mr. Sean Cahill
Associate Project Engineer
Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, California 95051

Re: K983220
Stryker InfraVision
Esophageal Kit
Regulatory Class: II
21 CFR §876.5365
Product Code: 78 FAT
Dated: February 24, 1999
Received: March 8, 1999

Dear Mr. Cahill:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, 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.

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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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,

CAPT Daniel G. Schultz, M.D.
Acting 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): K983220

Device Name: Stryker InfraVision™ Esophageal Kit

Indications For Use:

The Stryker InfraVision™ Esophageal Kit is an esophageal transillumination dilation device with a reusable illumination source, and a combined single use disposable fiberoptic light guide, nasogastric tube and balloon dilation system. The Stryker InfraVision™ Esophageal Kit is intended to transilluminate and dilate the esophagus during the fundoplication procedure as well as other thoracoscopic, laparoscopic, or open surgical procedures. Transillumination is intended to help the surgeon identify organs and placement of medical devices within body tissue.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983220