stryker
ENDOSCOPY
2590 Walsh Avenue
Santa Clara, CA 95051
(408) 567-
1-800-435-0111

OCT 27 1999

K993045

Attachment 6

510(k) Summary
Safety and Efficacy

Device Name
Current Classification Name(s):
Endoscope 21 CFR 876.1500 Class II
Common and Usual Name: Laparoscope
Proprietary Name: Stryker Bariatric Laparoscope

Device Sponsor:

Stryker Endoscopy
2590 Walsh Ave.
Santa Clara, CA 95051

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

The Stryker Bariatric Laparoscope is a design modification to the Stryker Laparoscope, K910132 of 2/21/91. The useful length of the device has been increased to a length appropriate for laparoscopic surgery on morbidly obese patients.

The Stryker Bariatric Laparoscope is a reusable rigid endoscope, packaged in the not-sterile state.

The Stryker Bariatric Laparoscope is cleaned and sterilized by the user prior to all uses. The device has been demonstrated to be sterilizable with a sterility assurance level (SAL) of 10-6 under a variety of recommended sterilization methods commonly available to health care facilities, including: ethylene oxide, steam autoclave, Sterrad and Steris.

The Stryker Bariatric Laparoscope is constructed of materials which are tested for biocompatibility per ISO 10993 and CDRH G95-1 guidance; these materials are safe, effective and durable for their intended purposes.

The Stryker Bariatric Laparoscope conforms to the electrical safety requirements of IEC 601-2-18 as a type BF or type CF applied part of medical electrical equipment.

The Stryker Bariatric Laparoscope has been evaluated to ensure equivalent optical performance to the predicate device.

The Stryker Bariatric Laparoscope has been evaluated to ensure equivalent mechanical strength and rigidity under loads normally expected in laparoscopic surgery.

The Stryker Bariatric Laparoscope does not introduce new issues when compared to its predicate device or uses. Therefore the Stryker Bariatric Laparoscope is considered to be substantially equivalent to its predicate device and uses.

R. H. Dahla
Associate Project Engineer
Stryker Endoscopy

9-7-99
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 1999

Mr. Robert H. Dahla
Associate Project Engineer
Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, California 95051

Re: K993045
Trade Name: Stryker Bariatric Laparoscope
Regulatory Class: II
Product Code: GCJ
Dated: September 10, 1999
Received: September 10, 1999

Dear Mr. Dahla:

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 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2 K993045

Indications for Use Statement

510(k) Number:

Device Name: Stryker Bariatric Laparoscope

Indications for Use:

Laparoscopes are intended to be used by surgeons in diagnostic and therapeutic procedures. Laparoscopic minimally invasive procedures are performed in the abdominal cavity by means of small skin punctures that allow the insertion of the laparoscope and laparoscopic instruments. This includes, but is not limited to such uses as gallbladder and appendix removal, hernia repair, gastric bypass, laparoscopic Nissen and examination of the abdominal cavity, appendix, gallbladder and liver.

Bariatric laparoscopes allow surgeons to perform procedures on morbidly obese segments of their patient population.

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 General Restorative Devices
510(k) Number K993045