

SEP 22 1998

APPENDIX F

K982542

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stryker[®]

ENDOSCOPY 2590 Walsh Ave. Santa Clara, CA 95051

SUMMARY SAFETY AND EFFICACY

Device Name

Current Classification Name(s):

Fiberoptic light ureteral catheters under 21 CFR 876.4020 by the Gastroenterology-Urology Devices Panel.

Common and Usual Name:

Stryker Ureteral Kit II or U-kit II

Proprietary Name:

Stryker Ureteral Illuminator System III

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 Ureteral Illuminator System III is an ureteral transillumination device with a reusable illumination source and a fiberoptic light ureteral catheter kit which is provided sterile for single use disposable application. The Stryker Ureteral Illuminator System III is intended to be used to transilluminate the ureter during laparoscopic and open surgical procedures. Transillumination is intended to help the surgeon identify the ureter(s) during open or laparoscopic surgical procedures of the lower abdomen or pelvic areas. The Stryker Ureteral Illuminator System III illumination source will comply with UL 544 Standard for Medical and Dental Equipment and 21 CFR 1040.10 Performance Standards for Lasers.

The Stryker Ureteral Illuminator System III fiberoptic light ureteral catheter kit will be constructed of materials which are tested for biocompatibility per ISO 10993 and are safe, effective, and durable for their intended purposes. The Stryker Ureteral Illuminator System III EtO sterilization processes are validated per AAMI/ANSI/ISO 11135, to a SAL of 10^{-6} .

The Stryker Ureteral Illuminator System III is equivalent in safety and effectiveness to a variety of devices currently marketed (Gabriel Ureteral Illuminator System II - K945088) which are used in the applications noted above for general transillumination purposes.

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

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1998

Mr. Sean Cahill
Design Engineer
Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, CA 95051

Re: K982542
Stryker Ureteral Illuminator System III
Dated: July 17, 1998
Received: July 21, 1998
Regulatory Class: II
21 CFR 876.4020/Procode: 78 FCS

Dear Mr. Cahill:

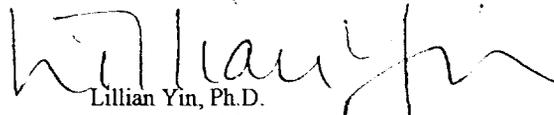
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

510(k) Number (if known): _____

Device Name: Stryker Ureteral Illuminator System III

Indications For Use:

The Stryker Ureteral Illuminator System III is an ureteral transillumination device with a reusable illumination source and a fiberoptic light ureteral catheter kit which is provided sterile for single use disposable application. The Stryker Ureteral Illuminator System III is intended to be used to transilluminate the ureter during laparoscopic and open surgical procedures. Transillumination is intended to help the surgeon identify the ureter(s) during open or laparoscopic surgical procedures of the lower abdomen or pelvic areas. As a general surgery transillumination device, the Stryker Ureteral Illuminator System III replaces and is substantially equivalent to existing predicate fiberoptic light ureteral catheter transillumination devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

OR Over-The-Counter Use _____

David A. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number 1K982542