DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Stryker Endoscopy
Mr. Christopher L. Cook
Quality Engineer
5900 Optical Court
San Jose, CA 95138

JUL 27 2015

Re: K040390
Trade/Device Name: Stryker Urology and Gynecology Hardware System
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH, FAJ, FAS and KQT
Dated (Date on orig SE ltr): February 10, 2004
Received (Date on orig SE ltr): February 17, 2004

Dear Mr. Cook,

This letter corrects our substantially equivalent letter of May 17, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: Stryker Urology and Gynecology Hardware System

Indications for Use:

The Stryker Urology and Gynecology Hardware System is intended to provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures. Examples of use of the product include the visualization and manipulation of anatomy, ablation, biopsy, incision, and resection of tissue, and/or as the surgeon deems appropriate. The system is intended for use in general urological and gynecological surgery through the minimally invasive approach, by utilizing natural orifices to access the surgical site. The system's use is intended for, but not limited to the following types of procedures:

Dilation of the urethra, and cold-slitting of urethral strictures
Trans-urethral incision and resection of the prostate
Trans-urethral removal of bladder tumors
Trans-cervical resection and ablation of the endometrium
Trans-cervical resection of fibroids

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040390

MAY 17 2004

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Proprietary Name:	Stryker Urology and Gynecology Hardware System
Common and Usual Name:	Scope, Obturator, Working Element, Sheath, Bridge, Electrode, Albarran Deflector, Timberlake Obturator, Cutting Loop, Roller Ball, Cold Knives, Dilator/Sound/Bougie, Bladder Syringe, Ellik Evacuator, Forceps
Classification Name:	Endoscope and accessories, Cystoscopes, Hysteroscope, Resectoscope, Sheaths, Electrode, Urethrotome, Dilators, Evacuator, Non-Electric Biopsy Forceps, G-U, Surgical Instruments

The Stryker Urology and Gynecology Hardware System is substantially equivalent in terms of safety and effectiveness to many currently marketed devices and surgery systems currently marketed by Henke Sass Wolf, Omnitech Systems, GIMMI, and ACMI.

The Stryker Urology and Gynecology Hardware System is an extension of the Hystero-Resectoscope and Accessories as currently marketed by Stryker and OEM suppliers Henke Sass Wolf and Omnitech Systems. The Stryker Urology and Gynecology Hardware System is composed of endoscopes, sheaths, accessories, and applied parts which provide the user with the means for endoscopic diagnostic and therapeutic surgical procedures.

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Trans-cervical resection of fibroids

Contraindications:

Acute Pelvic Inflammatory Disorder (PID)

Hysteroscopy may be contraindicated by the following conditions, depending on their severity or extent:

Inability to distend the uterus
Cervical stenosis
Cervical/vaginal infection
Uterine bleeding or menses
Known pregnancy
Invasive carcinoma of the cervix
Recent uterine perforation

The Stryker Urology and Gynecology Hardware System conforms to the following voluntary safety and performance standards: IEC 60601-1 Medical Electrical Equipment – General Requirements for Safety, IEC 60601-2-2 Medical Electrical Equipment – General Requirements for Safety, Collateral Standard, Electromagnetic Compatibility, IEC 60601-2-18 Particular Requirements for the Safety of Endoscopic Equipment, ANSI/AAMI HF-18 Electrosurgical Devices, ISO 10993 Biological Evaluation of Medical Devices.

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There are no significant technological or performance differences between the Stryker Urology and Gynecology Hardware System and the identified predicate devices and surgery systems, nor are there any new questions raised regarding safety or effectiveness, therefore, the Stryker Urology and Gynecology Hardware System is substantially equivalent to the identified predicate devices and surgery systems.

Contact:

Christopher L. Cook Date:

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