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510(k) Summary Statement
For the Laserscope Guided Delivery Device (GDD) Cystourethroscope & Accessories

General Information:

A. **Trade Name:**
Laserscope Guided Delivery Device (GDD) Cystourethroscope & Accessories

B. **Common Name:**
Cystourethroscope and Accessories

C. **Classification Name:**
Endoscope and accessories, Cystoscopes, Resectoscope, Sheaths, Evacuator, G-U, Surgical Instruments.
The following regulations apply: 21 CFR § 876.1500 (Endoscope and Accessories); 21 CFR § 876.4370 (Gastroenterology- Urology Evacuator)

D. **Establishment Registration Number:**
2937094

E. **Manufacturer's Identification:**
Laserscope
3070 Orchard Drive
San Jose, CA 95134-2011
(800) 243-9384 ext. 6795

Official Correspondent:
Paul H. Hardiman
Manager, Regulatory Affairs/Clinical Affairs

F. **Performance Standards:**
The Laserscope GDD Cystourethroscope conforms to the following performance standards: ANSI/AAMI ST81:2004; AAMI TIR12:2004; AAMI TIR30:2003; ISO 8600-4:1997; ISO 60601-2-18:1996; ISO 8600-1:1997;

G. **Product Code:**
78 KOG

H. **Predicate Devices:**
Stryker Urology and Gynecology Hardware System

I. **Indications For Use:**
The Laserscope GDD Cystourethroscope 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 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

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- Trans-urethral incision, vaporization, and resection of the prostate
- Trans-urethral coagulation, vaporization, fulguration, and resection of bladder tumors

J. **Device Description:**
The 24 Fr GDD Cystourethroscope is designed with a continuous flow outer sheath, a separate inner sheath/bridge, and an obturator. The outer sheath has the inflow and outflow Stopcocks attached to it. The inner sheath/bridge has one integral accessory port and can accommodate one accessory up to 9 Fr in size. The obturator is designed to allow atromatic introduction of the outer sheath in a natural orfice.

The true continuous flow design washes away blood and small tissue particles to ensure a clear operative field. The working length is 23.2 cm to allow access to the entire lower urinary tract. The dedicated operative channel stabilizes accessories including laser fibers. The Continuous Flow Laser Cystourethroscope is designed to be used with low viscosity fluids, including normal saline, Glycine, Sorbitol, or Ringer's Lactate, and standard surgical accessories.

K. **Clinical Data:**
No clinical tests were performed.

L. **Rationale for Substantial Equivalence & Safety:**
The Laserscope GDD Cystourethroscope & Accessories share the same Indications For use, similar design, materials, component features, and functional features, and therefore is substantially equivalent to the Stryker Urology and Gynecology Hardware System. There are no new issues raised regarding the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 27 2006

Laserscope
% Ms. Patricia L. Murphy
Responsible Third Party Official
KEMA Quality B.V.
4377 County Line Road
CHALFONT PA 18914

Re: K061646
Trade/Device Name: Laserscope GDD Cystourethroscope Hardware System and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: June 12, 2006
Received: June 12, 2006

Dear Ms. Murphy:

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.

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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061646

Device Name: Laserscope GDD Cystourethroscope Hardware System and Accessories

Indications For Use:

The Laserscope GDD Cystourethroscope 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 surgery through 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 strictures

Trans-urethral incision, vaporization, and resection of the prostrate

Trans-urethral removal of bladder tumors

Prescription Use ___√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061646