GENICON
NEW IDEAS FOR MODERN HEALTH CARE

NOV 1 2 2004

K041967

Section 2 – 510K Summary

Date Prepared – October 24, 2004

Trade Name – Genicon Laparoscopic Suction Irrigation

Common Name – Suction Irrigation

Classification - Class II – CFR 878.4400

Predicate Device – Stryker (K963646)

Product Description – The Genicon Laparoscopic Suction Irrigator system is indicated for use in patients undergoing a laparoscopic surgical procedure. It is designed to deliver sterile irrigation fluids to surgical sites during laparoscopic procedures and to evacuate blood, tissue debris, and smoke from the surgical site.

The system consists of a hand piece equipped with two trumpet style valves, a probe, and connecting lines of tubing, one set designed to attach to a supply of irrigation fluid, and the other designed to attach to an aspiration pump. The valves allow controlled irrigation and aspiration during a surgical procedure.

The hand piece of the suction irrigator is designed to allow instruments to be introduced through the suction irrigation probe to reach the operative site. The instrument adapter is adjustable to allow a variety of instruments and diameters.

It is a single use, disposable device and is sold sterile, and the probes may be available as single use or reusable depending on the purpose.

TEL 407.657.4851 — WWW.GENICONENDO.COM — FAX 407.677.9773
US OFFICE - 6869 Stapoint Court #114, Winter Park, Florida USA 32792 — EU OFFICE - 44 Airedale Avenue, Chriswick, London U.K W4 2NW

GENICON

NEW IDEAS FOR MODERN HEALTH CARE

Indications for Use – The GeniCon Laparoscopic Suction/Irrigation System is available with an array of probe designs to facilitate lavage during laparoscopic surgery. This device has applications in laparoscopic gynecologic, general, thoracic and urology procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.

Performance – There are no performance standards for this product.

Conclusion – Based on the indications for use and technological characteristics, the Genicon Suction Irrigation system has shown to be safe and effective for its intended use and substantially equivalent to the predicate devices.

Regards,

Gary W. Haberland
Product Manager

TEL 407.657.4851 — WWW.GENICONENDO.COM — FAX 407.677.9773
US OFFICE - 6869 Stapoint Court #114, Winter Park, Florida USA 32792 — EU OFFICE - 44 Airedale Avenue, Chriswick, London U.K W4 2NW

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 2004

Mr. Gary W. Haberland
Product Manager
GeniCon
427 Lake Howell
Maitland, Florida 32751

Re: K041967
Trade/Device Name: GeniCon Laparoscopic Suction Irrigation
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: September 20, 2004
Received: October 5, 2004

Dear:

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 (PMA), 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 (240) 276-0115. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

Indications for Use

510(k) Number (if known): K041967

Device Name: GeniCon Laparoscopic Irrigation System

Indications For Use:

The GeniCon Laparoscopic Suction/Irrigation System is available with an array of probe designs to facilitate lavage during laparoscopic surgery. This device has applications in laparoscopic gynecologic, general, thoracic and urology procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.

Prescription Use ___X___ 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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041967