GeniCon™

"New Ideas for Modern Healthcare"

JUN 19 2003

K 030174

Section II: 510(k) Summary

GeniCon, L.C.
Contact: Gary Haberland
P.O. Box 780038
Orlando, Florida 32878-0038
Telephone: 407.273.7619
Facsimile: 407.306.9356

Date Prepared: April 3rd, 2003

Trade Name: GeniCon Platinum Series Laparoscope
Common Name: Laparoscope

Classification Name: According to Section 513 of the Federal Food, Drug, Cosmetic Act, the device classification is Class II, performance Standards (21 CFR 878.4800)

Predicate Device: Surgical Image Laparoscope

Product Description: The GeniCon Platinum Series Laparoscope is a reusable device with a glass rod lens assembly that connects an eyepiece to a viewing lens on the distal end of the scope encompassed within a stainless steel shaft. Surrounding the glass rod assembly and contained with the stainless steel shaft is a series of light fibers that transfer light energy to illumination into the body cavity being viewed.

Indications for Use: The GeniCon Laparoscope is available in 3.5mm, 5mm and 10mm diameters with working lengths of 28cm to 44cm. This device has applications in gynecologic, general, thoracic and urology Endoscopic procedures to establish visualization for viewing an interior cavity of the body.

Performance: The FDA has not adopted performance standards for this product.

Conclusion: Based on the indications for use and technological characteristics, the GeniCon Platinum Series Laparoscope has been shown to be effective for its intended use and substantially equivalent to the predicate device.

US Office
GeniCon L.C.
P.O. Box 780038
Orlando, Florida U.S.A. 32878
Telephone: (321) 662-8603
Telefax: (407) 306-9356
E-Mail: USA@geniconendo.com

EU Office
GeniCon Europe Ltd.
44 Airedale Avenue
Chiswick, London U.K.
'4 2NW
Europe@geniconendo.com

Latin America Office
GeniCon
Calle 10 Sur No 50FF-28 Off 209
Medellin, Columbia
Telephone: 57.4.361.7557
Telefax: 57.4.285.2287
E-Mail: Latin@geniconendo.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2003

Mr. Gary Haberland
Product Manager
GeniCon L.C.
P.O. Box 780038
Orlando, Florida 32878-0038

Re: K030174
Trade/Device Name: Laparoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 3, 2003
Received: April 7, 2003

Dear Mr. Haberland:

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 (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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

510(k): K030174

Section I. Indications for Use Page: I-1

Device Name: Laparoscope

Indications for Use:

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

Prescription Use ✓ OR Over the Counter Use_____

(Optional Format 1-2-96)

Miriam C. Provost

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

510(k) Number K030174