JUN 2 0 2000

GeniCon L.C.
Contact: Gary Haberland
573 Waterscape Way
Orlando, FL 32828
Phone: (407) 273-7619
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Date Prepared: October 19, 1999

Trade Name: GeniCon Pneumo-Needle
Common Name: Veress Needle
Classification Name: According to Section 513 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards (21 CFR 884.1730).

Predicate Device: Apple Medical's Pneumo-Matic Insufflation Needle
580 Main Street
Bolton, MA 01740

Product Description:

The GeniCon, Pneumo-Needle is a sterile, disposable Veress needle which is available in 120mm or 150mm length. The device is equipped with a spring-loaded, round-tipped obturator. In addition, there is a "slide switch" which permits easy ON-OFF control of the gas flow. The most proximal end contains a malue luer lock connector for secure CO2 gas line connection.

Indications for Use:

The GeniCon Pnuemo – Needle is intended for percutaneous insertion into the peritoneal cavity for the purspose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

Performance:

A series performance tests were performed on the GeniCon Pneumo-Needle to inspect such areas as:

1. Tip Pull Test
2. Switch Operation
3. Spring Obturator Operation
4. Needle Puncture Force Test

Conclusion:

Based on the indications for use, technological characteristics and performance testing, the GeniCon Pneumo-Needle has been shown to be effective for its intended use and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2000

Mr. Gary Haberland
Product Manager
GeniCon L.C.
573 Waterscape Way
Orlando, FL 32828

Re: K993625
GeniCon Pneumo-Needle
Dated: March 31, 2000
Received: April 3, 2000
Regulatory Class: II
21 CFR §884.1730/Procode: 85 HIF

Dear Mr. Haberland:

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 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). 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) 594-4591. 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 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Section I. Indications for Use

510 (k) Number: unassigned K993625

Device Name: GeniCon Pneumo - Needle

Indications for Use:

The GeniCon Pneumo – Needle is intended for percutaneous insertion into the peritoneal cavity for the purspose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

(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)

David A. Ferguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993625