K991382

JUL 15 1999

Section II. 510(k) Summary

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

Trade Name: GeniCon Trocar/Cannula System
Common Name: Trocar
Classification Name: Trocar (per CFR 870.1390)

The intended use of this device is for laparoscopic surgery by general, thoracic, gynecologic and urological surgeons.

The legally marketed device to which we are claiming previous acceptance of predicate device is the LifeQuest Point Gard and Dexide trocars both in sizes 2.5,5, 7/8, 10, 12mm systems.

Engineering testing has demonstrated that the valve assembly performs better than that of the Life Quest and Core trocar valve assembly. This testing incorporated a simulated human abdominal cavity and the method of insertion of the device and use with various common laparoscopic instruments. In all areas of performance, this device performed equal to if not superior in pressure testing, ease of use and insertion.

This device incorporates several design features which facilitate the surgeons use both during insertion and while instrumentation is being inserted and manipulated.

Trocar Tip:

- A modified single slit tip to provide easier insertion for the surgeon by enabling the tip to minimally incise the tissue while providing a lower profile transition from the stainless tip to the cannula.

Trocar Handle:

- Enlarged to provide a more positive fit in the surgeon's palm during insertion, and provides a groove to provide a more positive fit for the thumb during removal or re-insertion.

Cannula:

- Trapezoidal fascia threads, they provide an easier insertion while a positive anchoring during instrument use.
- CO^2 port with male luer cap provides a "finger grip" during device insertion while the male luer cap is easier to remove and replace than the Apple silicone cap.
- Double wall valve lock, assists in maintaining the valve position and to alleviate the premature release sometimes experienced by the Apple product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 1999

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

Re: K991382
Trade Name: GeniCon Trocar Cannula System
Regulatory Class: II
Product Code: GCJ
Dated: April 19, 1999
Received: April 21, 1999

Dear Mr. Haberland:

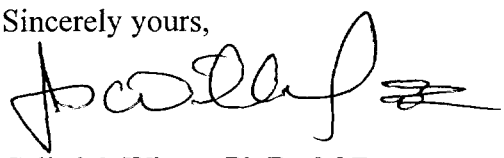
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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) 594-4595. 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" (21 CFR 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/dsmamain.html".

Sincerely yours,



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

Enclosure

K991382

Section I. Indications for Use

510 (k) Number: unassigned

Device Name: Trocar

Indications for Use:

The GeniCon trocar is available in 2.5, 5, 7/8, 10 and 12mm diameter with a mono-slit stainless tip. This trocar has application in gynecologic, general, thoracic and urology endoscopic procedures to establish a port of entry for instrumentation.

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

Prescription Use X OR Over-The-Counter Use_____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991382