AUG 19 1999

990324

510(k) Summary
as required by 807.92(c)
for Funnel Trocar™
Prepared July 9, 1999

Submitted by: Patton Medical Corporation
1000 Westbank Drive, Suite 5A200
Austin, Texas 78746
512 916-4880 Fax 512 916-4881

Contact Person: Michael T. Patton
President

Device Trade Name: **Funnel Trocar™**

Common Name: Disposable Surgical Trocar/Cannula

Classification: Laparoscope, General & Plastic Surgery, § 876.1500, Class II

Predicate Devices: **Sabre Ultimate Shielded Trocar System** (K943976), manufactured by Endoscopic Concepts Incorporated, 11 Forest Park Drive, Mendon, MA 01756.

Laparoscopic Trocar (K901407, K911813, K950457, K953409, K953903), manufactured by Core Dynamics, Inc., P.O. Box 16351, Jacksonville, FL 32245.

Description of Device:

The **Funnel Trocar™** is a disposable single patient use device fabricated from surgical grade stainless steel, and biocompatible medical grade polymers. The device is available in a variety of diameters (5mm, 7/8mm, 10mm, 12mm) and lengths (55mm, 70mm, and 100mm). The **Funnel Trocar™** is supplied with either a shielded or non-shielded cutting obturator (trocar). The cannula is equipped with a luer fitting to provide access for insufflation of the operative area. The cannula is available with or without stability threads.

Intended Use of Device:

The **Funnel Trocar™** is an access device for laparoscopic procedures. The new instrument creates and maintains a passageway for laparoscopic instruments during a variety of general, gynecologic, thoracic, and urological procedures.

Substantial Equivalence to Predicate Device:

The **Funnel Trocar™** shielded version is substantially equivalent to the **Sabre Ultimate Shielded Trocar System** (K943976), manufactured by Endoscopic Concepts Incorporated, 11 Forest Park Drive, Mendon, MA 01756. The **Funnel Trocar™** non-shielded version is substantially equivalent to the **Laparoscopic Trocar** (K901407, K911813, K950457, K953409, K953903), manufactured by Core Dynamics, Inc., P.O. Box 16351, Jacksonville, FL 32245.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1999

Mr. Michael T. Patton
President
Patton Medical Corporation
1000 Westbank Drive
Suite 5A200
Austin, Texas 78746

Re: K992324
Trade Name: Funnel Trocar™
Regulatory Class: II
Product Code: GCJ
Dated: July 9, 1999
Received: July 12, 1999

Dear Mr. Patton:

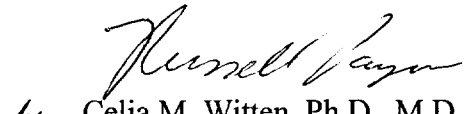
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



for 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

510(k) NUMBER (IF KNOWN): K992324

DEVICE NAME: Funnel Trocar™

INDICATIONS FOR USE:

Intended Use of Device:

The **Funnel Trocar™** is an access device for laparoscopic procedures. The new instrument creates and maintains a passageway for laparoscopic instruments during a variety of general, gynecologic, thoracic, and urological procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-
(Per 21 CFR 801.109) (Optional Forma

Russell P. Pagan 8/21/99

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992324