K060629

APR 7 2006

510(k) SUMMARY

**510(k) NUMBER:** PENDING

**SUBMITTED BY:** Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA-92688
(949) 713-8000

**CONTACT PERSON:** Cheryl Blake
Vice President, Regulatory Affairs and Quality Systems

**DATE OF PREPARATION:** February 7, 2006

**NAME OF DEVICE:** Blunt Tip Trocar System

**CLASSIFICATION NAME:** Laparoscope, General & Plastic Surgery (21CFR 876.1500)

**TRADE NAME:** GelPort® Blunt Tip Trocar System

**PREDICATE DEVICE:** United States Surgical Blunt Tip Trocar (K924011)
Originally filed under Origin Medsystems, Incorporated

**INTENDED USE:** The GelPort Blunt Tip Trocar System is indicated for use in general, abdominal, gynecological and thoracic minimally invasive surgical procedures to establish a path of entry or to gain access through tissue planes, extraperitoneal spaces and/or potential spaces for endoscopic instruments.

**DEVICE DESCRIPTION:** The GelPort Blunt Tip Trocar System is a sterile single use device, intended for use in conjunction with Applied's currently marketed Trocar products. A standard trocar assembly consists of an obturator, a seal and a cannula system.

**PERFORMANCE DATA SUMMARY**: The performance and functional testing of the GelPort Blunt Tip Trocar System compared to its predicate device demonstrated that the GelPort Blunt Tip Trocar System is substantially equivalent to its predicate device and it introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2006

Applied Medical Resources Corp.
c/o Underwriters Laboratories, Inc.
Mr. Morten Simon Christensen
Staff Engineer & FDA Office Coordinator
455 E. Trimble Road
San Jose, California 95131-1230

Re: K060629
Trade/Device Name: GelPort® Blunt Tip Trocar System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 28, 2006
Received: March 29, 2006

Dear Mr. Christensen:

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,

Mark N. Melkerson
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): _____

Device Name: ____GelPort® Blunt Tip Trocar System_____

Indications for Use:

The GelPort Blunt Tip Trocar System is indicated for use in general, abdominal, gynecological and thoracic minimally invasive surgical procedures to establish a path of entry or to gain access through tissue planes, extraperitoneal spaces and/or potential spaces for endoscopic instruments.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K060629