K083638

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510(k) SUMMARY

DEC 23 2008

SUBMITTED BY: Applied Medical Resources Corporation
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DATE OF PREPARATION: November 6, 2008

TRADE NAME: To be determined

COMMON NAME: Trocars, Trocar Systems, Access Systems

CLASSIFICATION NAME: Laparoscope, General & Plastic Surgery
(21CFR 876.1500, product code GCJ)

PREDICATE DEVICE: Applied Medical Modular Trocar System (K060096)

DEVICE DESCRIPTION: This filing addresses a line extension to the Modular Trocar System approved in K060096.

A typical trocar access system consists of a seal, a cannula and an obturator. The obturator is used to place the cannula (with seal attached) through the patient's abdomen, then it's discarded. To function properly, the cannula must not shift from its location in the abdomen as the surgery proceeds. For that reason, many cannulas have structural features that help anchor the cannula in the tissue. These features may range from a textured surface to ridges on the outer diameter of the cannula. The line extension that is the topic of this filing offers trocar models that have an alternate method of anchoring the cannula to abdominal tissue. For descriptive purposes in this document, these trocar models may at times be referred to as "Fixation Trocars".

Since the seal and the obturator of the Fixation Trocar are unchanged from the predicate device approved in K060096, this filing primarily addresses the cannula and the features that allow the new anchoring method. A technical description of those features is in "SUMMARY OF TECHNOLOGICAL CHARACTERISTICS" on page 2-2.

The Fixation Trocar will be available in cannula diameters ranging from 5mm to 15mm and lengths ranging from 55mm to 150mm. These dimensions match the trocars approved in K060096.

INTENDED USE: The Fixation Trocar is a sterile, single-use device, intended for use in conjunction with APPLIED's currently marketed trocar products to establish a path of entry for endoscopic instruments for use during general, abdominal, gynecological and thoracic minimally invasive procedures or to gain access through tissue planes and/or potential spaces for endoscopic instruments. The Fixation Trocar may be used with an optical tissue separator or a bladed obturator, and with or without visualization for primary and secondary insertions.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS: The objective of the line extension is to offer trocar models that provide an alternate method of anchoring the trocar cannula to the patient's abdominal wall. The Fixation Trocar design has an inflatable balloon that is mounted at the cannula tip. Once the cannula tip is positioned inside the patient's abdominal cavity, the balloon is inflated thus preventing the cannula from unintended movement out of the patient. To prevent unintended movement into the patient, a movable bolster located on the cannula portion outside the patient is advanced until it contacts the patient's skin. The balloon/bolster combination - in effect - anchors the cannula to the abdominal wall, thus preventing undesirable shifting as the surgery proceeds. See Fig 1.

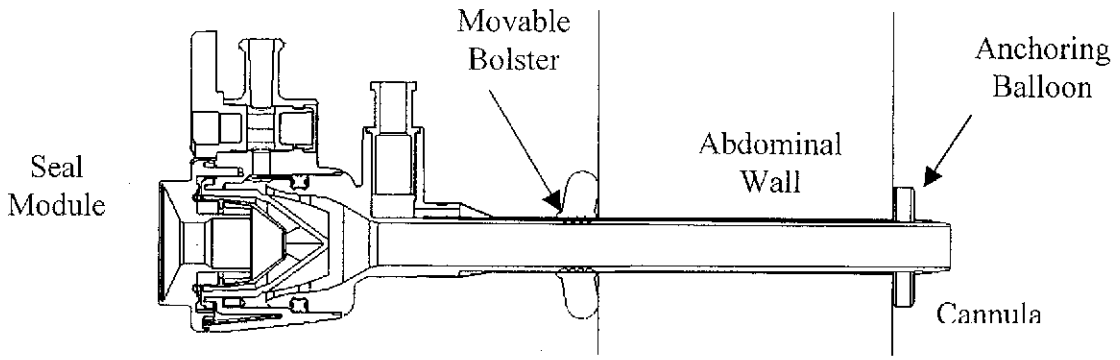

Fig 1 Cutaway of Fixation Trocar in tissue

The predicate trocar cannula in K060096 also had an anchoring feature, a series of ridges on the external surface. These ridges, or threads, are designed to provide a degree of resistance to unintended cannula movement. See Fig 2.

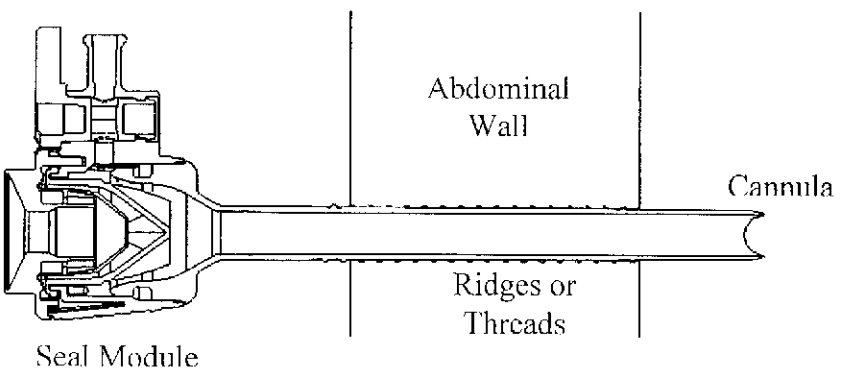

Fig 2 Trocar in tissue with threads (ridges) on cannula surface

DISCUSSION OF NONCLINICAL TESTS SUBMITTED: There are no currently recognized standards that specify anchoring security of trocar cannulas. For that reason, APPLIED created a test protocol designed to confirm safety and efficacy of the Fixation Trocar relative to the predicate device of K060096. These tests include a determination of:

- Insertion force - the force required to insert the trocar cannula and obturator through abdominal tissue.
- Post-insertion migration/slippage force - the force required to dislodge the trocar cannula from its position in tissue before the anchoring feature is activated.
- Retention force - the force required to dislodge the cannula from tissue after deployment of the balloon.
- Removal force - the force required to remove the trocar from tissue after collapse of the balloon.

These tests were performed on the subject device as well as predicate devices. For a discussion of the test method and results, see section 15.

CONCLUSIONS DRAWN FROM TESTING: APPLIED's performance and functional testing demonstrated that the Fixation Trocar is substantially equivalent or superior to its predicate devices and introduces no new safety and effectiveness issues when used as instructed. The Fixation Trocar's anchoring feature performs particularly well in its most important characteristic, retention of the cannula in the patient's abdomen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2008

Applied Medical Resources Corporation
% Underwriters Laboratories, Inc.
Mr. Morten Christensen
455 East Trimble Road
San Jose, California 95131-1230

Re: K083638
Trade/Device Name: Fixation Trocars
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: December 8, 2008
Received: December 9, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

K083638

INDICATIONS FOR USE

510(k) Number (if known): Not yet assigned.

Device Name: Modular Trocar System; trade name not yet assigned.

Indications for Use: Applied Medical Modular Trocar Systems are sterile, single-use devices consisting of an obturator, a cannula and seal. These systems are 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 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K083638