OCT 5 ˇ 2007

K072674

510(k) SUMMARY

510(k) NUMBER: PENDING

SUBMITTED BY:
Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA-92688
(949) 713-8000
(949) 713-8205 (FAX)

CONTACT PERSON:
Frans VandenBroek
Vice President, Regulatory Affairs
fvandenbroek@appliedmedical.com

DATE OF PREPARATION: August 24, 2007

NAME OF DEVICE: Modular Trocar System

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

TRADE NAME: Kii Shielded Access System

PREDICATE DEVICE: Applied Medical Modular Trocar System (K060096)
Applied Medical Disposable Surgical Trocar (K943489)
Ethicon Bladed Shielded System (K971475)

INTENDED USE: The Modular Trocar System 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 Modular Trocar System may be used with an optical separator or a bladed obturator, and may be used with or without visualization for primary and secondary insertions.

DEVICE DESCRIPTION: A typical trocar access system consists of a seal, a cannula and an obturator. This filing applies to a change to the access system approved in K060096. The change involves offering the option of a second obturator design. The optional obturator has a cutting blade covered by a retractable shield. De-activation of the shield is accomplished by moving a switch on the obturator handle. The design concept and materials of the optional obturator are similar to those approved in APPLIED's Disposable Surgical Trocar 510(k) K943489. The method of de-activation of the shield is similar to the method used in the Ethicon Bladed Shielded system approved in K971475.

Differences between the subject device and the device approved in K943489 are primarily in the shape of the obturator cutting blades. The subject device has a flat blade whereas the devices approved in K943489 have either flat or tri-pointed blades.

The blade design and its sharpness affects insertion forces needed to advance the trocar through tissue. As described in the test reports in Appendix III, insertion forces comparing the subject device to the APPLIED predicate device of K943489 demonstrated substantially equivalence.

The materials used in the subject device are polymers and stainless steels, as is the case with the predicate devices.

The Modular Trocar System will be available in sizes ranging from 5mm to 12mm diameter and in lengths ranging from 55mm to 150mm. These dimensions match the trocars approved in K060096.

PERFORMANCE DATA SUMMARY: The performance and functional testing of the Modular Trocar System, as modified for this filing, included tests to verify:

- Insertion Force
- Shield Mechanism Reliability
- Shield Deployment Time
- Locking Mechanism Structural Strength Test.

These tests were performed on the subject device as well as predicate devices. The performance and functional testing demonstrated that the Modular Trocar System with shielded bladed obturator, is substantially equivalent to its predicate devices and 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

Applied Medical Resources Corp.
% Underwriters Laboratories, Inc.
Mr. Jeff D. Rongero
12 Laboratory Drive
Research Triangle, NC 27709

OCT 5 " 2007

Re: K072674
Trade/Device Name: Kii Trocar System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: September 18, 2007
Received: September 21, 2007

Dear Mr. Rongero:

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.

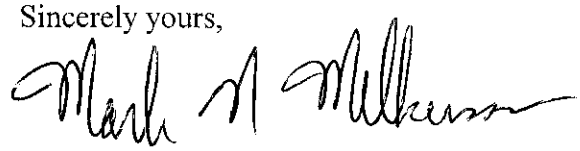
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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

INDICATIONS FOR USE

510(k) Number (if known): K072674

Device Name: Modular Trocar System

Indications for Use:
The Applied Medical Modular Trocar System is a sterile, single-use device consisting of a bladed, shielded obturator, a cannula and seal. The obturator and seal may also be used with reusable APPLIED cannulas that may be made of stainless steel or DuraGold® polymer. The obturator is 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.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Mark N Milliken

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

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