JAN 24 2006

K060096

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:	December 21, 2005
NAME OF DEVICE:	Modular Trocar System
CLASSIFICATION NAME:	Laparoscope, General & Plastic Surgery (21CFR 876.1500)
TRADE NAME:	Modular Trocar System
PREDICATE DEVICE:	Applied Medical Modular Trocar (K932995) Applied Medical Optical Separator (K032889) Applied Medical, Rancho Santa Margarita, CA

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 System may be used with an Optical Separator and may be used with or without visualization for primary and secondary insertions.

DEVICE DESCRIPTION: The Modular 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.

The Modular Trocar System will be available in sizes of 5mm, 8mm, 11mm, 12 mm and 15mm diameter in lengths ranging from 55mm to 150mm.

PERFORMANCE DATA SUMMARY: The performance and functional testing of the Modular Trocar System included tests to verify the inflation and leakage as compared to its predicate devices. The performance and functional testing demonstrated that the Modular Trocar System is substantially equivalent to its predicate devices and it introduces no new safety and effectiveness issues when used as instructed.

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K060096 Third Party Organization: UL

Third Party's Primary Reviewer(s): Morten Christensen

ODE/OIVD Division: DGRND Branch/Team: GSDB

Section 2 – 510(k) Decision

Third party recommendation: SE ✓ NSE ___ Other (specify): ___

ODE/OIVD final decision: SE ✓ NSE ___ Other (specify): ___

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review	✓		
b. Extent of pre-submission consultation with ODE/OIVD division	✓		
c. Organization and format of review documentation	✓		
d. Determination of 510(k) administrative completeness (screening review)	✓		
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	✓		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences	✓		
g. Rationale for conclusions and recommendation	✓		
h. Use of guidance documents and standards	✓		
i. Resolution of 510(k) deficiencies and FDA requests for additional information	✓		
j. Scope of reviewer expertise and use of consulting reviewers	✓		
k. Other (specify):			

Comments (explanation of ratings/issues): ___

Section 4 – ODE/OIVD Assessor Information

Assessed by: [signature] Date: 1/23/06 Tel. No.: 4-1307 x192

Routing: Division--Clip completed assessment (this page only) to inside front cover of 510(k).
DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2006

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

Re: K060096
Trade/Device Name: Modular Trocar System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: January 12, 2006
Received: January 13, 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.

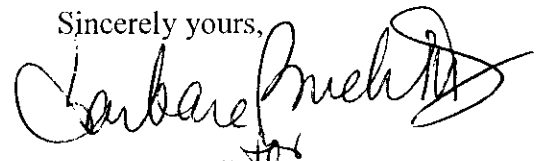
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (21 CFR 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/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting 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): K060096

Device Name: Modular Trocar System

Indications for Use:

The Applied Medical Modular Trocar System is a sterile single use device, or may be used with a reusable stainless steel or reusable DuraGold® cannula and 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. If utilizing the Applied Medical Optical Separator Obturator with the Modular Trocar System it may be used with or without visualization for primary and secondary insertions.

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)

Barbara Ruehrwein for MPA

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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