K032889

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OCT - 2 2003

510(k) SUMMARY

510(k) NUMBER: PENDING

SUBMITTED BY:

Applied Medical Resources Corporation
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CONTACT PERSON:

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DATE OF PREPARATION: August 27, 2003

NAME OF DEVICE: Optical Separator

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

TRADE NAME: Optical Separator

PREDICATE DEVICE: EndoPath Optiview Optical Surgical Obturator, Ethicon-Endo-Surgery, Inc. Cincinnati, OH. (K990028)
Applied Medical Dilating Tip Obturator
Applied Medical, Rancho Santa Margarita, CA
(K012884)

INTENDED USE: The Optical Separator 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 Optical Separator may be used with or without visualization for primary and secondary insertions.

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DEVICE DESCRIPTION: The Optical Separator 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. Traditional obturators use a blade for cutting to establish a path of entry through the several layers of tissue. The Optical Separator dilates and separates tissue along its natural fiber lines in its path of entry.

The Optical Separator will be available in sizes of 5mm, 8mm, 11mm and 12mm diameter and in lengths ranging from 55mm to 150mm.

The use of the Optical Separator, which separates tissue along its natural fibers versus cutting of tissue by traditional bladed trocars is expected to reduce trauma to vessels and the abdominal wall and minimize the risk of organ puncture. Upon removal of the trocar at the end of the procedure the separated tissue is expected to reapproximate, leaving a smaller, linear defect.

PERFORMANCE DATA SUMMARY: The performance and functional testing of the Optical Separator included tests to verify the insertion force and tests to verify its reliability and visualization during use. The performance and functional testing demonstrated that the Optical Separator is substantially equivalent to its predicate devices 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

OCT - 2 2003

Applied Medical Resources
c/o Ms. Ellen Fickewirth
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050-4269

Re: K032889
Trade/Device Name: Optical Separator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: September 15, 2003
Received: September 17, 2003

Dear Ms. Fickewirth:

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 (301) 594-4659. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K032889

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Optical Separator "Indications for Use" as required.

510(k) Number: Not assigned

Device Name: Optical Separator

Indications for Use: The Optical Separator 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 and/or potential spaces for endoscopic instruments.

Signature: _____ Title: *Director of RA/Clinical Programs* Date: *8-27-03*

Miriam C Provost

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

510(k) Number K032889

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)