

SEP 14 2004

510(k) SUMMARY

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**510(k) NUMBER:**

PENDING K041795

**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:**

June 30, 2004

**NAME OF DEVICE:**

Optical Separator System

**CLASSIFICATION NAME:**

Laparoscope, General & Plastic Surgery (21CFR 876.1500)

**TRADE NAME:**

Optical Separator System

**PREDICATE DEVICE:**

Applied Medical Optical Separator (K032889)  
Applied Medical Insufflation Needle (K963359)  
Applied Medical, Rancho Santa Margarita, CA

**INTENDED USE:** The Optical Separator 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 Optical Separator System may be used with or without visualization for primary and secondary insertions, and as a means of insufflating the peritoneum prior to laparoscopic procedures.

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

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

The use of the Optical Separator System, 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 System 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 System is substantially equivalent to its predicate devices and it introduces no new safety and effectiveness issues when used as instructed.



SEP 14 2004

Ms. Cheryl Blake  
Vice President, Regulatory Affairs  
and Quality Systems  
Applied Medical Resources Corporation  
22872 Avenida Empresa  
Rancho Santa Margarita, California 92688

Re: K041795  
Trade/Device Name: Optical Separator System  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: GCJ  
Dated: June 30, 2004  
Received: July 2, 2004

Dear Ms. Blake:

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.

Page 2 - Ms. Cheryl Blake

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,

*for Miriam C. Provost*

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

INDICATIONS FOR USE

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

510(k) Number: ~~Not assigned~~ K041795

Device Name: Optical Separator System

Indications for Use: The Optical Separator 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 and/or potential spaces for endoscopic instruments, and as a means of insufflating the peritoneum prior to laparoscopic procedures.

Signature:  Title: Vice President RA and Quality Systems Date: 6/30/2004

Prescription Use X  
(Per 21 CFR 801.109)

OR Over-The -Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

510(k) - ODE/FDA  
Optical Separator  
June 2004

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
**(Division Sign-Off)**  
**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number** K041795