K012968

DEC 0 3 2001

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:	Anil Bhalani Vice President of Regulatory Affairs and Clinical Programs
DATE OF PREPARATION:	August 31, 2001
NAME OF DEVICE:	Trocar Seal
CLASSIFICATION NAME:	Laparoscope, General & Plastic Surgery (21CFR 876.1500)
TRADE NAME:	Applied Access Seal
PREDICATE DEVICE:	Premium Disposable Seal, Applied Medical Resources (K932995)

INTENDED USE: The Applied Access Seal is a sterile single use device, intended for use in conjunction with Applied's currently marketed Trocar products for use as a port of entry for endoscopic or surgical instruments during general, abdominal, gynecological and thoracic minimally invasive procedures.

DEVICE DESCRIPTION: A standard trocar assembly consists of an obturator, a seal and a cannula system. The Applied Access Seal is designed for use with Applied Medical's Cannulas and Obturators. An Applied Medical Trocar will consist of the Applied Access Seal, a cannula and an obturator.

The Applied Access Seal when used in laparoscopic surgery is designed to maintain pneumoperitoneum or positive pressure at its distal end to prevent loss of surgical gas. The device is designed to seal around surgical instruments, which are typically inserted through the device during surgery, to prevent loss of pneumoperitoneum during use and exchange of such instruments. The Applied Access seal is available with a stop-cock through which carbon dioxide or other gas may be dispensed into the surgical site during laparoscopic surgery.

The Applied Access Seal is made from materials used in currently marketed medical devices and has passed biocompatibility testing required per ISO 10993-1.

PERFORMANCE DATA SUMMARY: The performance and functional testing of the Applied Access Seal included tests to verify integrity of seal and leakage through the seal. The performance and functional testing demonstrated that the Applied Access Seal is substantially equivalent to its predicate device 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

DEC 0 3 2001

Mr. Anil Bhalani
Vice President of Regulatory Affairs
and Clinical Programs
Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K012968
Trade/Device Name: Applied Access Seal
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 31, 2001
Received: September 4, 2001

Dear Mr. Bhalani:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Susan Walker

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

INDICATIONS FOR USE

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

510(k) Number: Not assigned K012968

Device Name: Applied Access Seal

Indications for Use: The Applied Access Seal is a sterile single use device, indicated for use in conjunction with Applied's currently marketed Trocar products where a port of entry is desired for endoscopic or surgical instruments during general, abdominal, gynecological and thoracic minimally invasive procedures.

(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)

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

510(k) Number K012968