510(k) SUMMARY

JAN 19 2007

510(k) NUMBER:	K062907
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 27, 2006
NAME OF DEVICE:	Wound Retractor
CLASSIFICATION NAME:	Drape, Surgical, General & Plastic Surgery. (Regulation Number 21CFR 878.4370, Surgical drape and drape accessories). Retractor, Manual Surgical (Regulation number 878.4800 Manual surgical instruments for general surgical use (retractor), and 884.4520 Obstetric-gynecological general manual instruments.
TRADE NAME:	Alexis® Wound Retractors
PREDICATE DEVICE:	OB/Mobius Apple Medical Corp. 28 Lord Road, Unit 135 Marlboro, MA 01752
DESCRIPTION:	The Applied Wound Retractor consists of a flexible polymer membrane formed into the shape of a cylinder. Attached to each open end of the cylinder are two semi-rigid polymer rings.

SUMMARY STATEMENT: The Applied Alexis Wound Retractor (large and extra large size only) is indicated for use to assist in non-urgent cesarean deliveries that are routine procedures. It is intended to provide incision retraction and to protect against open wound contamination during a cesarean section. It is indicated for use as a surgical retractor for both vertical and transverse incisions.

To perform these functions, Alexis Wound Retractors are constructed as a cylindrical membrane sheath that has two rings attached to each open end. The rings are molded in a plastic material. The Wound Retractor package also includes an incision template.

The Wound Retractor is simple to set up and easy to use. A sterile skin marker is used to mark an incision line at the surgery site and the incision is made. The Wound Protecting sheath is placed in position through the incision with one ring inside the abdomen. The external ring is placed in traction and folded over itself until it contacts the abdomen. Once securely in place, the Alexis Wound Retractor keeps the incision open during the procedure. The wound protective sheath lines the incision and protects against wound contamination during the procedure.

The Alexis Wound Retractor has been found non-toxic and non-irritant when tested in accordance with ISO 10993, Part I: Biological Evaluation of Medical Devices. The materials used in the manufacturing of the Alexis Wound Retractor have been tested in accordance with applicable standards and was determined to pass tensile strength, elongation, (ASTM D 412) and Tear Strength (ASTM D 624). Functional performance testing has been completed and has passed the required testing.

The Applied Wound Retractor is a disposable, single-use device and is packaged inside a Tyvek/Mylar peel pouch, which is standard packaging material for Applied's products. The packaged product is then placed in an outer product shelf pack.

The Applied Wound Retractor is sterilized using 100% EO. Applied's 100% EO sterilization cycle provides a sterility assurance level of 10^{-6}. Sterilization validation for Applied Medical's EO cycle uses three half-cycle validation runs, which incorporate biological indicators and temperature monitors distributed throughout the load to verify gas penetration and profile temperature distribution. Spore strip biological indicators of *Bacillus Atrophaeus* with a population of 10^6 are used to monitor routine finished product sterilization loads. Sterilant residue levels will be in compliance with ANSI/AAMI/ISO 10993-7:1995 for limited exposure devices which is 20 mg ethylene oxide and 12 mg ethylene chlorohydrin.

The Alexis Wound Retractor is substantially equivalent to predicate devices in design methodology, principle of operation and clinical utility. The device introduces no new safety or effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JAN 9 2007

Ms. Cheryl Blake
Vice President Regulatory Affairs
Applied Medical Resources
22872 Avenida Empresa
RANCHO SANTA MARGARITA CA 92688

Re: K062907
Trade/Device Name: Alexis Wound Retractor
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: II
Product Code: KNA and GAD
Dated: December 29, 2006
Received: January 3, 2006

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 (Premarket Approval), 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K062907

Device Name: Alexis Wound Retractor

Indication For Use:

The Alexis Wound Retractor (large and extra large size only) is indicated for use to provide abdominal access during routine non-urgent cesarean deliveries.

The Alexis Wound Retractor was previously cleared for the following *general* indications for use (K041711):

- Access the abdominal cavity during surgery through an atraumatically retracted incision.
- Delivery maximum exposure of the abdominal cavity with minimum incision size.
- Protect against wound contamination during laparoscopic and open surgery.
- Seal off the incision opening to permit insufflating the peritoneum.
- Convert the incision wound to an additional trocar port site.
- Access the thoracic cavity or other soft tissue retraction during cardiac and general surgical procedures through an atraumatically-retracted incision.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062907