K113268

510(k) SUMMARY

FEB 0 8 2013

510(k) OWNERS NAME:	Applied Medical Resources Corporation 22872 Avenida Empresa Rancho Santa Margarita, CA-92688 (949) 713-8000 (949) 713-8205 (FAX)
CONTACT PERSON:	Frans VandenBroek fvandenbroek@appliedmedical.com
DATE OF PREPARATION:	January 25, 2013
TRADE NAME:	Alexis® O Wound Protector/retractor models C8405 and C8406
COMMON NAME:	Wound protector/retractor
CLASSIFICATION NAME:	Surgical drape and drape accessory, General & Plastic Surgery. Class II, 21CFR §878.4370, Product Code KKX
PREDICATE DEVICE:	Applied Medical Alexis Wound Retractor (K031889)

DEVICE DESCRIPTION: Applied Medical's Alexis O wound protector/retractors are disposable single-use surgical devices used to establish access to internal body cavities and spaces. The protector/retractors are designed for soft tissue retraction and provide 360 degrees of a circumferential retraction and 360 degrees of protection of the wound margins. The predicate Alexis devices are made in sizes ranging from Small to XLarge that accommodate incisions ranging from 2.5 to 17cm. This submission request clearance for adding an XXL and XXXL sizes to the product family. The XXL is for incisions ranging from 17 to 25cm; the XXXL is for incisions ranging from 25 to 30cm.

The protector/retractors have a shelf life of three years and are delivered with a template that is used to determine the incision length for the corresponding retractor chosen for the procedure. Protector/retractors are packaged in a Tyvek pouch placed inside a carton.

INTENDED USE: The Applied Medical Alexis wound protector/retractor models C8405 and C8406 have the same intended use as the predicate devices: accessing the abdominal cavity during surgery through an atraumatically retracted incision. The protector/retractors deliver maximum exposure of the abdominal cavity with minimum incision size and protect against wound contamination during laparoscopic and open surgery.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS: The Alexis O Wound protector/retractor has the same technological characteristics as the predicate devices of K031889. Predicate and proposed device are identical in design, principle of action and clinical utility. Both consist of a clear flexible membrane formed into a cylindrical sleeve with two semi-rigid polymer rings at each end. Alexis is placed by advancing one of the rings through an incision in the abdominal wall. The ring establishes the sheath's internal anchor.

The second ring remains outside the body and is placed in traction and repeatedly rolled over itself with the thumbs until the ring contacts the abdominal wall. The tension in the sheath retracts the abdominal tissue and the incision becomes a circular opening. Alexis allows access to the peritoneum while protecting the incised tissue from contamination and injury throughout the procedure.

DISCUSSION OF NONCLINICAL TESTS SUBMITTED: There are no FDA recognized standards that specify performance of wound protectors/retractors. For that reason, Applied Medical created non-clinical test protocols specifically designed to confirm substantial equivalence of the proposed device relative to the predicate device. In addition, the Alexis sheath was exposed to a microbial challenge per ANSI AAMI PN70; 2003/R 2009, "Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities." This standard determines a barrier classification level for protection against blood borne pathogens.

Testing included:

- Visual inspection to verify mechanical integrity of the device.
- Reliability (cycling) testing to verify the device can complete five activations without losing structural integrity.
- Wound retraction testing in simulated and in porcine tissue to verify the device retracts straight incisions into circular openings.
- Biocompatibility testing per ISO10993 (cytotoxicity, sensitization and irritation) to verify the device materials did not elicit a tissue response.
- Microbial performance testing per ANSI AAMI PN70; 2003/R 2009 to verify the device met the requirements of a level 4 surgical gown as defined by test method ASTM F1671, "Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood Borne Pathogens using Phi-X174 Bacteriophage Penetration as a Test System."

DISCUSSION OF CLINICAL TESTS SUBMITTED:

No clinical testing was performed on the subject devices. However, the following study, offered as supporting material, was performed using the predicate devices of K031889:

- Reid K., et al. Barrier wound protection Decreases Surgical Site Infection in Open Elective Colorectal Surgery: A Randomized Clinical Trial. Dis Colon Rectum. 2010 Oct; 53(10): 1374-1380

This randomized clinical trial compared the use of the Alexis wound retractor with standard retraction in open elective colorectal resectional surgery. One hundred thirty consecutive patients, 18 years and older, were randomly assigned to have either wound retraction/protection with Alexis (n=64) or standard wound retraction (n=66). Randomization was performed after the patient was anesthetized. The primary end point was the incidence of superficial or deep surgical site infection occurring within 30 days of the procedure as defined by the Centers for Disease Control and Prevention. The secondary end point was performance (effectiveness) of the Alexis wound protectors as assessed by participating surgeons.

The results revealed a clinically significant reduction in SSI in the trial population subjected to the Alexis device. SSI rate with Alexis was 4.7%, without, 22.7%. Seventy eight percent of the SSI events were diagnosed after discharge from the hospital and there was no difference in rates of reoperation, readmission or formal wound drainage between the two groups. There were no adverse effects or complications reported as a result of the Alexis device in any surgeries using the Alexis device. Seven of the 8 surgeons (78%) in the trial are adapting Alexis as part of their standard setup.

CONCLUSIONS DRAWN FROM TESTING: Applied Medical's testing demonstrated that the subject device is safe and effective, and performs as well as the predicate device of K031889.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 8, 2013

Mr. Frans Vandenbroek
Principal Regulatory Specialist
Applied Medical Resources Corporation
22872 Avenida Empresa
RANCHO SANTA MARGARITA CA 92688

Re: K113268
Trade/Device Name: Alexis O Wound Protector/Retractors, models C8405 and C8406
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: January 28, 2013
Received: January 30, 2013

Dear Mr. Vandenbroek:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

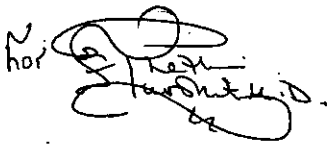
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): k113268

Device Name: Alexis O Wound Protector/Retractors, models C8405 and C8406

Indication for use: The Applied Wound Protector/Retractor is indicated for use to:

- Access the abdominal cavity during surgery through an atraumatically retracted incision.
- Deliver maximum exposure of the abdominal cavity with minimum incision size.
- Protect against wound contamination during laparoscopic and open surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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