K100120

APR - 2 2010

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510(k) SUMMARY

510(k) OWNERS NAME: Applied Medical Resources Corporation
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(949) 713-8000
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CONTACT PERSON: Frans VandenBroek
fvandenbroek@appliedmedical.com

DATE OF PREPARATION: January 11, 2010

TRADE NAME: Alexis Orthopaedic Wound Retractor

COMMON NAME: Wound retractor

CLASSIFICATION NAME: Surgical Drape and Drape Accessories, General & Plastic Surgery (21CFR 878.4370, Product Code KKX)

PREDICATE DEVICE: Applied Medical Alexis Wound Retractor

DEVICE DESCRIPTION: Wound retractors convert straight incisions into round openings that facilitate access to internal body cavities and spaces. APPLIED's wound retractors consist of a cylindrical flexible film sheath that has a semi-rigid polymer ring on each end. Retractors of this design are useful in open orthopaedic procedures that require unimpeded access while simultaneously protecting the wound.

INTENDED USE: Orthopaedic wound retractors are sterile, single-use devices that are intended to access the musculoskeletal system through an atraumatically retracted wound. The predicate device(s) are cleared for access to internal spaces and for soft tissue retraction. Orthopaedic procedures fall in the latter category.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS: The predicate and subject wound retractors share a common construction. Each 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. One ring is positioned inside a body cavity while the other remains outside the patient. Rolling down the outer ring towards the inner ring shortens the retractor and anchors the device in the patient. It also retracts the wound and converts the incision into a round opening. The flexible membrane that connects the rings protects the incised tissue throughout the procedure.

The subject device is essentially equivalent to the predicate except that the sheath material is sturdier to accommodate orthopaedic instruments. Further, whereas the diameters of the inner and outer rings of the predicate retractors are identical, some models of the orthopaedic retractor will feature an one ring smaller than the other.

DISCUSSION OF NONCLINICAL TESTS SUBMITTED: There are no recognized standards that specify performance of wound retractors of this type. For that reason, APPLIED created test protocols specifically designed to confirm safety and efficacy of the subject device relative to the predicate device of K062907. These tests include the device's:

- Ability to retract a wound
- Resistance to tearing during instrument exchanges
- Durability (cycling test)
- Maximum allowable incision size

These tests were performed on predicate and subject device and established substantial equivalence between the two.

CONCLUSIONS DRAWN FROM TESTING: APPLIED's functional and performance testing has demonstrated that the subject device is substantially equivalent or superior to its predicate device and introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Applied Medical Resources Corporation
% Mr. Frans VandenBroek
Vice President, Regulatory Affairs
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

APR - 2 2010

Re: K100120
Trade/Device Name: Alexis Orthopaedic Wound Retractor
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: January 11, 2010
Received: January 26, 2010

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.

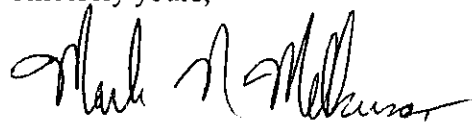
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): Not yet assigned. K100120

Device Name: Alexis Orthopaedic Wound Retractor

Indication for use: The Alexis Orthopaedic Wound Retractor is indicated for use to access the musculoskeletal system through an atraumatically retracted wound

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)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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