K093296

510(k) SUMMARY

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SUBMITTED BY:

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NOV - 5 2009

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DATE OF PREPARATION: July 22, 2009

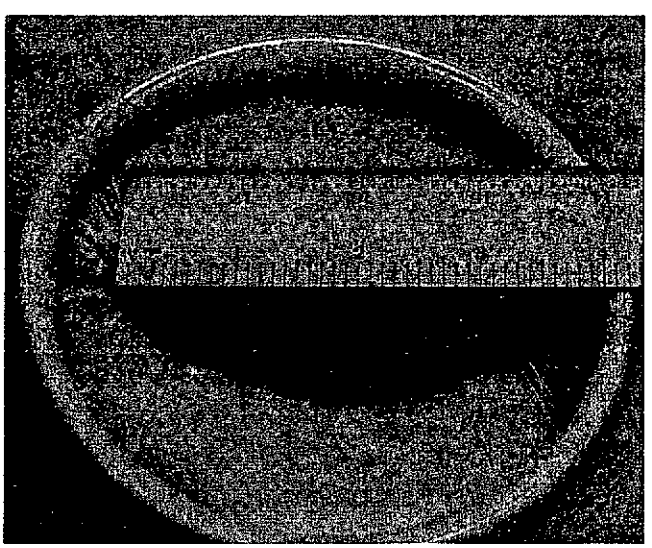
TRADE NAME: Alexis Laparoscopic System

COMMON NAME: Wound Retractor

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

PREDICATE DEVICE: Applied Alexis Wound Retractor, K041711

DEVICE DESCRIPTION: Wound retractors convert straight incisions into semi round openings that facilitate access to internal body cavities and operative sites. These retractors are particularly useful in open or laparoscopic procedures that require removal of large quantities of tissue.



INTENDED USE: The Alexis Laparoscopic System 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.
- Seal off the incision opening to permit insufflation of 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.

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 (the inner ring) is positioned inside a body cavity while the other (outer ring) remains outside the patient.

Rotating the outer ring inward - similar to rolling up a shirt sleeve - 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 has a snap-on silicone cap that closes and seals the wound opening. This allows the body cavity to be insufflated and the procedure to be completed under laparoscopic conditions. The center of the cap is designed to accommodate a 12mm trocar which effectively converts the wound retractor into a trocar port site.

For a more detailed description of retractor features, please see section 8.

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 (K041711). These tests include comparison of:

- The leak rate of the device when the retracted wound is closed.
- The leak rate of the device when the retracted wound is closed and when a trocar is in place.
- Force required to fasten and to detach the cap.
- Retention strength of inner (green) ring.
- Maximum retraction of wound.
- Sealing integrity during manipulation of trocars.
- Potential for trocars that are placed through the cap to inflict undue stress on wound.
- Flammability evaluation of cap material.

Several of these tests were performed on both predicate and subject devices. A discussion of the test methods and results are in Section 15.

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. The subject device gives surgeons a secondary method for sealing a wound that has been retracted and can also serve as an additional port site while still maintaining pneumoperitoneum.

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 Corp
% Underwriters Laboratories, Inc.
Morten Simon Christensen
455 E. Trimble Road
San Jose, California 95131

NOV - 5 2009

Re: K093296
Trade/Device Name: Alexis Laparoscopic System
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical drape and drape accessories
Regulatory Class: II
Product Code: KKX
Dated: October 19, 2009
Received: October 21, 2009

Dear Morten Simon Christensen:

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 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~~. K093296

Device Name: Alexis Laparoscopic System

Indication for use: The Alexis Laparoscopic System 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.
- Seal off the incision opening to permit insufflation of 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.

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)

for mxm

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

510(k) Number K093296