K100959

APR 22 2010

Applied Medical

510(k) SUMMARY

SUBMITTED BY: Applied Medical Resources Corporation
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CONTACT PERSON: Frans VandenBroek

DATE OF PREPARATION: February 9, 2010

TRADE NAME: Retrieval System

COMMON NAME: Tissue bags

CLASSIFICATION NAME: Laparoscope, General & Plastic Surgery (21CFR 876.1500, product code GCJ)

PREDICATE DEVICE: Applied Medical Inzii™ Retrieval System

DEVICE DESCRIPTION: The Applied medical specimen Retrieval System is a disposable receptacle used to collect and extract tissue, organs and calculi during laparoscopic procedures. It consists of a flexible polymer bag and an introducer structure that fits through a trocar port. Extracorporeal activation of the introducer handle ejects the flexible bag which automatically opens in preparation for receipt of the specimen. The device is constructed of various polymers and stainless steel. It is packaged in a Tyvek/Mylar peel pouch and a product shelf pack. The shelf pack will be sterilized using gamma irradiation per AAMI/ISO guidelines. Sterility Assurance Level will be 10^{-6}.

INTENDED USE: The Applied Medical specimen Retrieval System is indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS: The new device is a downsized version of the predicate and is designed to broaden Applied Medical's retrieval system product line. Both predicate and subject device feature a tissue bag and a delivery system consisting of an introducer tube and an ejection handle. Predicate and new device are constructed of the same materials and the design is similar except for a reduction in introducer tube diameter to accommodate placement through a smaller trocar. The subject device bag also has a smaller volume.

DISCUSSION OF NONCLINICAL TESTS SUBMITTED: Applied Medical created a dedicated test method designed to confirm safety and efficacy of the subject device relative to the predicate device of K060051. These tests focused on functionality, robustness and bag strength. Test results for predicate and new device are essentially the same.

CONCLUSIONS DRAWN FROM TESTING: Applied's performance and functional testing demonstrated that the subject specimen retrieval system is substantially equivalent to the predicate device of K060051 and introduces no new safety and effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Applied Medical Resources
% Underwriters Laboratories, Inc.
Casey Conry
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Melville, New York 11747

APR 22 2010

Re: K100959
Trade/Device Name: Specimen Retrieval System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: April 05, 2010
Received: April 07, 2010

Dear Casey Conry:

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

Device Name: Specimen Retrieval System

Indications for Use: The Applied Medical Specimen Retrieval System is indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.

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

510(k) Number K100959