DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 23, 2014

Applied Medical Resources Corporation
Ms. Aeree Lee
Regulatory Affairs Specialist
22872 Avenida Empresa
Rancho Santa Margarita, California 92688

Re: K142427
Trade/Device Name: Applied Medical Tissue Containment System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 21, 2014
Received: November 24, 2014

Dear Ms. Lee:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142427

Device Name
Applied Medical Tissue Containment System

Indications for Use *(Describe)*
The Applied Medical Tissue Containment System is indicated to contain and isolate tissue during, or prior to, surgical removal and/or extracorporeal manual morcellation.

Contraindications:
The Tissue Containment System is contraindicated for laparoscopic power morcellation during gynecologic procedures.

The Tissue Containment System is contraindicated for use with powered cutting devices (e.g., power morcellators, electrosurgical and laser instruments), and when, in the judgment of the physician, use of such a device would be contrary to the best interest of the patient.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(K) Submitter:
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Date of Preparation: August 28, 2014

Trade Name: Applied Medical Tissue Containment System

Common Name: Tissue Bag

Classification:
Accessory to Endoscope, Class II
Product Code: GCJ Regulation: 21 CFR 876.1500

Predicate Device:
Applied Medical Specimen Retrieval System
510(k)#: K060051
Product Code: GCJ Regulation: 21 CFR 876.1500

Cook LapSac Tissue Entrapment Pouch
510(k)#: K910914
Product Code: KGY Regulation: 21 CFR 878.4100

Device Description: The Applied Medical Tissue Containment System is a flexible tissue bag that includes an attached tether and guard accessory. The subject system is provided sterile.

The Tissue Containment System is used to contain and isolate specimens for surgical removal and/or manual morcellation. After the device is fully inserted into the abdominal or pelvic cavity, the mouth of the bag returns to its original, circular shape, facilitating placement of the specimen in the bag. When the specimen is ready for removal and/or manual morcellation, the tether is used to maneuver the ring to the surface of the

extraction site.

If the specimen requires manual morcellation, the ring may be repeatedly flipped to shorten the bag and consequently bring the specimen closer to the extraction site. The guard is placed in the bag opening prior to manual morcellation, providing a robust barrier between the bag and sharp instruments.

Intended Use: The Applied Medical Tissue Containment System is indicated to contain and isolate tissue during, or prior to, surgical removal and/or extracorporeal manual morcellation.

The Tissue Containment System is contraindicated for laparoscopic power morcellation during gynecologic procedures.

The Tissue Containment System is contraindicated for use with powered cutting devices (e.g., power morcellators, electrosurgical and laser instruments), and when, in the judgment of the physician, use of such a device would be contrary to the best interest of the patient.

Comparison of Technological Characteristics with the Predicate Device:

The subject and predicate devices are both tissue bags intended to retrieve and contain specimens during manual morcellation. Both devices are wholly inserted into the abdominal or pelvic cavity prior to specimen placement in the bag. If the specimen requires morcellation, both bags are brought up to the extraction site prior to morcellation.

The following technological differences exist between the subject and predicate devices:

- Mechanism of the bag opening
- Use of different materials
- Addition of a guard in subject device

Discussion of Performance Testing:

The following performance data is provided in support of the substantial equivalence determination.

Biocompatibility

The biocompatibility evaluation for the Applied Medical Tissue Containment System was conducted in accordance with the FDA G95-1 Blue Book Memo, the FDA Draft Guidance "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'", and the International Standard ISO 10993-1. The subject

device is a device that contacts tissue for a duration of less than 24 hours and the following tests were considered:

- Cytotoxicity
- Irritation
- Sensitization

All materials were found to be biocompatible.

Mechanical Testing

Side-by-side bench top testing was performed with the subject and predicate devices to demonstrate substantial equivalence. The bench top tests were designed to focus on the functional performance of the specimen containment and retrieval features, as well as its use during morcellation. Both subject and predicate devices were evaluated for:

- Bag seam integrity
- Tether break force
- Puncture resistance

Additional testing was performed on the subject device to evaluate the device functionality:

- Dye penetration
- Viral penetration
- Bubble leak
- Simulated use

Conclusions:

Results of testing demonstrates that the subject Tissue Containment System is substantially equivalent to the predicates Applied Medical Specimen Retrieval System and Cook LapSac Tissue Entrapment Pouch, and that the subject device performs comparably to the current marketed device for the same intended use.