K103510

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510(k) Summary

5.1 Type of Submission: Traditional

5.2 Submitter:

Address:	8F-2, No. 127, Lane 235, Pao Chiao Rd., Hsin Tien City, Taipei, Taiwan
Phone:	886-2-89191698
Fax:	886-2-89191528
Contact:	Sophia Chiu

Establishment Registration Number: 3007791595

5.3 Identification of the Device:

Proprietary/Trade name:	Unimax Specimen Retrieval System
Common Name:	Tissue Bags
Classification Name:	laparoscope, general & plastic surgery
Device Classification:	II
Regulation Number:	876.1500
Panel:	General & Plastic Surgery
Product Code:	GCJ

5.4 Identification of the Predicate Device:

Predicate Device Name:	Specimen Retrieval System
Manufacturer:	Applied Medical Resources Corporation

510(k) Number or Clearance Information: K100959

5.5 Intended Use and Indications for Use of the subject device.

The Unimax 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.

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5.6 Device Description

The Unimax Specimen Retrieval System is a sterile and single-use specimen container designed for use in retrieving specimens during endoscopic surgery. The Unimax Specimen Retrieval System is supplied in a dispending tube for ease of insertion through a standard 10, 11 or 12mm trocar sheath.

5.7 Non-clinical Testing

A series of in vitro and in vivo preclinical physical, mechanical and biocompatibility tests were performed to assess the safety and effectiveness of the Unimax Specimen Retrieval System. All the test results demonstrate the performance of Unimax Specimen Retrieval System meets the requirements of its pre-defined acceptance criteria and intended uses. The results of the non-clinical testing demonstrate that the Unimax Specimen Retrieval System is as safe and effective as the predicate devices.

5.8 Safety and Effectiveness

The result of bench testing indicates that the new device is as safe and effective as the predicate device.

5.9 Substantial Equivalence Determination

The Unimax Specimen Retrieval System submitted in this 510(k) file is substantially equivalent in intended use, design, principles of operation, materials and performance to the cleared Applied Medical Specimen Retrieval System which is the subject of K100959. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

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Item	**Predicate Device** (Applied Medical Resources Corporation Specimen Retrieval System)	**Proposed Device** (Unimax Medical Systems Inc. Specimen Retrieval System)
Similarity		
Intended Use	Indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.	Same
Material	Various Polymer Stainless	Same
Specification	consists of a flexible polymer bag and an introducer structure that fits through a trocar port	Same
Biocompatibility	ISO 10993-1: 2003, Biological evaluation of medical devices -- Part 1: Evaluation and testing ISO 10993-10: 2002, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity ISO 10993-12: 2007, Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials	Same
Difference		
Sterilization	gamma irradiation, Sterility Assurance Level will be 10^{-6}	EtO Sterilization

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5.10 Conclusion

After analyzing bench tests, it can be concluded that Unimax Specimen Retrieval System is as safe and effective as the predicate device.

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

MAY - 6 2011

Unimax Medical Systems, Inc.
% Acmebiotechs Co., Ltd.
Mr. Michael Lee
No. 45, Minshen Road, Danshui Town
Taipei County (Taiwan) 251
China

Re: K103510
Trade/Device Name: Unimax Specimen Retrieval System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 11, 2011
Received: April 11, 2011

Dear Mr. 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 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,

for

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): K103510

Device Name: Unimax Specimen Retrieval System

Indications for Use:

The Unimax 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___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R.P. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103510