510(k) Summary

5.1 Type of Submission: Traditional

5.2 Preparation Date: Apr 29, 2011

5.3 Revised Date: Jul 27, 2011

5.4 Submitter: Unimax Medical Systems Inc.

Address: 8F-2, No. 127, Lane 235, Pao Chiao Rd., Hsin Tien, Taipei, Taiwan

Phone: 886-2-89191698

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Contact: Sophia Chiu

Establishment Registration Number: 3007791595

5.5 Identification of the Device:

Proprietary/Trade name:	Unimax Veress Needle
Common Name:	Veress Needle
Classification Name:	Insufflator, Laparoscopic
Device Classification:	2
Regulation Number:	884.1730
Panel:	Obstetrics/Gynecology
Product Code:	HIF

5.6 Identification of the Predicate Device:

Predicate Device Name:	GeniCon Pneumo-Needle
Manufacturer:	GeniCon, L.C.

510(k) Number or Clearance Information: K993625

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

The Unimax Veress Needle is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.

5.8 Device Description

The Unimax Veress Needle is a sterile and single-use product. It incorporated a spring loaded blunt stylet mechanism similar to the needle. It is used to establish peritoneum prior to trocar and cannula insertion in laparoscopic procedures. The Veress Needle, available in 120mm and 150mm lengths, has applications in gynecological laparoscopy and other laparoscopic procedures.

5.9 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 Veress Needle. The tests listed below were conducted in accordance with **ISO 10993-1 Biological evaluation of medical devices- Part 1: Evaluation and testing, ISO 10993-5 Biological Evalustion of medical devices- Part 5: Test for in vitro cytotoxicity, ISO 10993-7 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals, ISO 10993-10 Biological evaluation of medical devices- Part10: Tests for irritation and delayed-type hypersensitivity, ISO 10993-12 Biological evaluation of medical devices- PArt12: Sample preparation and reference material, ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.**

- Cytotoxicity Test
- Intracutaneous Reactivity Test
- Maximization Sensitization Test
- EO Sterilization Validation Study Report
- Ethylene Oxide Sterilization Residuals Study Report

The tests listed below have demonstrated that the subject device performs at least same performance as the predicate device.

- Tip Pull Test
- Switch Operation
- Spring Obturator Operation
- Needle Puncture Force Test

All the test results demonstrate the performance of Unimax Veress Needle meets the requirements of its pre-defined acceptance criteria and intended uses.
The results of the non-clinical testing demonstrate that the Unimax Veress Needle is as safe and effective as the predicate devices.

5.10 Substantial Equivalence Determination

The Unimax Veress Needle submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared GeniCon Pneumo-Needle which is the subject of K993625. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Item	Proposed Device (Unimax Medical Systems Inc. Veress Needle)	Predicate Device (GeniCon L.C. Pneumo-Needle)
Intended Use	The Unimax Veress Needle is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.	The GeniCon Pneumo-Needle is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic procedures.
Consisted Instruments	Veress Needle Obturator	Veress Needle Obturator
Models	xVN Series	Model 900-200
Dimension	120mm, 150mm	120mm, 150mm

Sterilization	EO Sterilized	EO Sterilized
Safety standards	ISO 10993-1 ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 10993-12 ISO 11135-1	ISO 10993-1 ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 10993-12 ISO 11135-1
Performance standards	Not Applicable	Not Applicable
Compared performance testing	Tip Pull Test Switch Operation Spring Obturator Operation Needle Puncture Force Test	Tip Pull Test Switch Operation Spring Obturator Operation Needle Puncture Force Test

5.11 Conclusion

After analyzing bench tests, safety testing data, it can be concluded that Unimax Veress Needle is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Unimax Medical Systems Inc.
% Mr. Michael Lee, President
AcmeBiotechs Co., Ltd.
No.45, Minsheng Rd. Danshui Town
TAIPEI COUNTY 251
TAIWAN

Re: K111441
Trade/Device Name: Unimax Veress Needle
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF, FHO
Dated: May 20, 2011
Received: May 24, 2011

AUG 19 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,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111441

Device Name: Unimax Veress Needle

Indications For Use:

The Unimax Veress Needle is intended for percutaneous insertion into the peritoneal cavity for the purpose of insufflation with carbon dioxide to establish pneumoperitoneum prior to the placement of trocars during laparoscopic 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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111441