K112358

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OCT 17 2011

510(k) Summary

5.1 **Type of Submission:** Traditional

5.2 **Preparation Date:** Aug 9, 2011

5.3 **Revised Date:**

5.4 **Submitter:** Unimax Medical Systems Inc.

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Contact: Sophia Chiu

Establishment Registration Number: 3007791595

5.5 **Identification of the Device:**

Proprietary/Trade name:	Unimax Trocar System Model: Auto-Locking Trocar, Bladeless Trocar, Visible Trocar, Hasson Trocar, Dilating Trocar, Secondary Trocar, Thoracic Trocar
Common Name:	Disposable Surgical Trocar/Cannula
Classification Name:	Laparoscope, General & Plastic Surgery
Device Classification:	II
Regulation Number:	876.1500
Panel:	General & Plastic Surgery
Product Code:	GCJ

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5.6 Identification of the Predicate Device:

Predicate Device Name:	ENDOPATH Bladeless Trocar, ENDOPATH Blunt Tip Trocar, ENDOPATH Dilating Tip Trocar
Manufacturer:	ETHICON ENDO-SURGERY, INC.
Product Code:	GCJ
510(k) Number:	K032676
Predicate Device Name:	Shielded Surgical Trocar
Manufacturer:	ETHICON ENDO-SURGERY, INC.
Product Code:	GCJ
510(k) Number:	K971475
Predicate Device Name:	ENDOPATH Disposable Thoracic Trocar Sleeve
Manufacturer:	ETHICON ENDO-SURGERY, INC.
Product Code:	GEA/GCJ
510(k) Number:	K920110

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

The Unimax Trocar System, Model: Auto-Locking Trocar, Bladeless Trocar, Visible Trocar, Hasson Trocar, Dilating Trocar, Secondary Trocar, and Thoracic Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.

5.8 Device Description

The Auto-locking Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments. The Auto-locking Trocar is available from 3-15mm. The cannula assembly has a universal seal, a valve, and a stopcock. This device has a bladed tip with an internal shield, which is designed to cover the cutting edges once the body cavity has been entered. The cannula assembly has universal seal and stopcock.

The Bladeless Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments. The Bladeless Trocar is available from 3-15mm The cannula assembly (10mm and 12mm type) has a universal seal, a valve, and a stpcock. The cannula assembly (5mm type) has a stopcock.

The Visible Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments. The Visible Trocar is available from 5-15mm. Visible Trocar allows direct visualization of the abdominal wall layers when the trocar is traversed, which offers a safe and rapid option of primary trocar. The cannula assembly has a universal seal, a valve, and a stopcock.

The Hasson Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments. The Hasson Trocar is available from 3-15mm. This device has a blunt tip, which is designed for open Laparoscopy. The cannula assembly has a fixation device, a universal seal, a valve, and a stopcock.

The Dilating Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoacopic instruments. The Dilating Trocar is available from 3-15mm. This device has a non-bladed conical tip which offers enhanced security to enter the abdomen. The cannula assembly has two-ply of seal and stopcock. There is a built-in universal seal.

The Secondary Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments. The Secondary Trocar is available in 2 different lengths: 5mm/7cm and 5mm/10cm. This device has a non-bladed conical tip which offers enhanced security to enter the abdomen. The cannula assembly has two-ply of seal and stopcock.

The Thoracic Trocar consists of a blunt-tipped obturator and a threaded cannula. It is designed for instrument stabilization and also protect against foreign materials entering the chest cavity. Once inserted into the chest, the Thoracic Trocar must be turned clockwise until it is securely seated in the tissue. There are four types of Thoracic Trocars: 6mm/7cm, 11mm/7cm, 13mm/7cm, and 15mm/7cm.

5.9 Non-clinical Testing

A series of safety tests were performed to assess the safety and effectiveness of the Unimax Trocar System. The safety tests were conducted in accordance with **ISO 10993-1, ISO 10993-5, ISO 10993-7, ISO 10993-10, ISO 10993-12, and ISO 11135-1.** The performance testing conducted on subject device and predicate device are listed below:

- Obturator Compatibility
- Insertion & Cannula Stability
- Air Leakage

All the test results demonstrate Unimax Trocar System meets the requirements of its pre-defined acceptance criteria and intended uses.

5.10 Substantial Equivalence Determination

The Unimax Trocar System submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared ENDOPATH Bladeless Trocar, ENDOPATH Blunt Tip Trocar, ENDOPATH Dilating Tip Trocar (K032676), Shielded Surgical Trocar (K971475), and ENDOPATH Disposable Thoracic Trocar Sleeve (K920110). Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Item	**Proposed Device (Unimax Trocar System)**	**Predicate Device (ENDOPATH Bladeless Trocar, Blunt Tip Trocar, Dilating Tip Trocar)**	**Predicate Device (Shielded Surgical Trocar)**	**Predicate Device (ENDOPATH Disposable Thoracic Trocar Sleeve)**
Models	Auto-locking		Shielded	
	Bladeless	Bladeless		
	Visible	Bladeless (Visible)		
	Hasson	Blunt Tip		
	Dilating	Dilating		
	Secondary			
	Thoracic			Thoracic

Comprised Elements	Cannula Tip of Obturator	Cannula Tip of Obturator	Cannula Tip of Obturator	Cannula Tip of Obturator
Dimension	Diameter:	Diameter:	Diameter:	Diameter:
	3-15mm	5-12mm	3-12mm	10mm
	Length:	Length:	Length:	Length:
	65-150mm	65-150mm	65-150mm	120mm
Sterilization	EO Sterilization	EO Sterilization	EO Sterilization	EO Sterilization
Safety standards	ISO 11135-1 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 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
Performance standards	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Performance Testing Item	Obturator Compatibility	Obturator Compatibility	Obturator Compatibility	Obturator Compatibility
	Insertion & Cannula Stability	Insertion & Cannula Stability	Insertion & Cannula Stability	Insertion & Cannula Stability
	Air Leakage	Air Leakage	Air Leakage	Air Leakage

5.11 Conclusion

After analyzing bench tests, safety testing data, it can be concluded tha: Unimax Trocar 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

Unimax Medical Systems, Inc.
% AcmeBiotechs Co., Ltd.
Mr. Michael Lee
No. 45, Minsheng Road
Danshui Town, Taipei County
Taiwan, China 251

FEB 10 2012

Re: K112358
Trade/Device Name: Unimax Trocar System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: August 11, 2011
Received: August 16, 2011

Dear Mr. Lee:

This is a corrected SE letter which was dated October 17, 2011.

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 Peter J. Pinto DSA CLIND.R

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112358

Indications for Use

510(k) Number (if known):

Device Name: Unimax Trocar System

Model: Auto-Locking Trocar, Bladeless Trocar, Visible Trocar, Hasson Trocar, Dilating Trocar, Secondary Trocar, Thoracic Trocar

Indications for Use:

The Unimax Trocar System, Model: Auto-Locking Trocar, Bladeless Trocar, Visible Trocar, Hasson Trocar, Dilating Trocar, Secondary Trocar, and Thoracic Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.

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)

Neil R P Ogden for mxn

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

510(k) Number K112358