DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 10, 2015

Unimicro Medical Systems (ShenZhen) Company, Ltd.
% Mr. Long Yang
Shenzhen Hlongmed Biotech Company, Ltd.
R15-08, East Building,Yihai Plaza, Chuangye Road, Nanshan District
518054 Shenzhen, Guangdong 518054
P.R.China

Re: K141594
Trade/Device Name: Unimicro Trocar Kit, models: Auto-Locking Trocar, Hasson Trocar, Bladeless Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 19, 2015
Received: June 29, 2015

Dear Mr. Yang:

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,

Joshua C. Nipper -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 on last page.

510(k) Number *(if known)*
K141594

Device Name
Unimicro Trocar Kit, models: Auto-Locking Trocar,Hasson Trocar,Bladeless Trocar

Indications for Use *(Describe)*
The Unimicro Trocar kit,Model: Auto-Locking Trocar,Hasson Trocar, and Bladeless Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Unimicro Medical Systems (ShenZhen) Co., Ltd.

510(K) SUMMARY

K141594

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Type of submission :Traditional

The assigned 510(K) number is:K141594

The date the summary was prepared: Jun 9,2014

1. Submitter information:

Manufacturer Name: Unimicro Medical Systems (ShenZhen) Co.,Ltd.

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2. Contact person:

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3. Identification of the Device :

Trade Name: Unimicro Trocar Kit

Model: Auto-Locking Trocar,Hasson Trocar,Bladeless Trocar

Common Name: Disposable Surgical Trocar /Cannla

Classification Name: Laparoscope, General & Plastic Surgery

Regulation Number:876.1500

Device Classification: II

Product Code:GCJ

4. Identification of the Predicative Device

Table 1: Predicative Device Information

Device Name	Common Name	Manufacturer	Classification and Code	Classification regulation	510(k) number
Unimax Trocar System	Disposable Surgical Trocar /Cannla	Unimax Medical Systems Inc.	Class Ⅱ, GCJ	21CFR 876.1500	K112358

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

The Unimicro Trocar kit,Model: Auto-Locking Trocar,Hasson Trocar, and Bladeless Trocar has application in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.

6. 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 in three (3) sizes: 5mm, 10mm and 12mm. 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 Hasson Trocar has application in a variety of endoscopic procedures to provide a port for entry for endoscopic instruments. The Hasson Trocar is available in two (2) sizes: 10mm and 12mm.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 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 5-12mm: The cannula assembly (10mm to 12mm type) has a universal seal, a valve, and a stopcock. The cannula assembly (5mm type) has a stopcock.

7. Non-clinical Testing

A series of safety tests were performed to assess the safety and effectiveness of the Unimicro Trocar kit. 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 Unimicro Trocar kit meet the requirements of its pre-defined acceptance criteria and intended uses.

8. Substantial Equivalence Determination

The Unimicro Trocar kit (Model: Auto-Locking Trocar,Hasson Trocar,Bladeless Trocar) submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Unimax Trocar System which is the subject of K112358. Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

The comparison to predicate device as below Table 2.

Table 2 : Comparison to Predicate Device

Item	**Proposed Device** Unimicro Trocar kit	**Predicate Device** Unimax Trocar System K112358
Classification regulation	21 CFR 876.1500	21 CFR 876.1500
Classification and Code	Class Ⅱ, GCJ	Class Ⅱ, GCJ
Device Classification Name	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery

Indications for Use	Applicate in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.	Applicate in a variety of endoscopic procedures to provide a port of entry for endoscopic instruments.
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
Compared elements	Cannula Tip of obturator	Cannula Tip of obturator
Performance testing item	Obturator compatibility	Obturator compatibility
	Insertion & cannula stability	Insertion & cannula stability
	Air leakage	Air leakage
Sterilization	EO Sterilized	EO Sterilized
Disposable	Yes	Yes
Model	Auto-Locking Trocar	Auto-Locking Trocar
	Hasson Trocar	Hasson Trocar
	Bladeless Trocar	Bladeless Trocar
	/	Visible Trocar
	/	Dilating Trocar
	/	Secondary Trocar
	/	Thoracic Trocar
Dimension	Diameter :5-12mm	Diameter :3-15mm
	Length :70-120mm	Length :65-150mm

9. Conclusion

After analyzing bench tests, safety testing data, it can be concluded that: Unimicro Trocar kit is as safe and effective as the predicate device.