DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 4, 2014

Unimicro Medical Systems Company, Ltd.
% Mr. Long Yang
Shenshen Hlongmed Biotech Company Ltd.
R15-08, East Building, Yihai Plaza, Chuangye Road, Nanshan District
Shenzhen, Guangdong 518054
People's Republic China

Re: K141592
Trade/Device Name: Unimicro Suction Irrigation Tubing set, models: Suction Irrigation Tubing Set A, Suction Irrigation Tubing Set B
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: June 20, 2014
Received: June 25, 2014

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,

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 on last page.

510(k) Number *(if known)* K141592

Device Name
Unimicro Suction Irrigation Tubing set, models : Suction Irrigation Tubing Set A , Suction Irrigation Tubing Set B

Indications for Use *(Describe)*
The Unimicro Suction Irrigation Tubing set is available with an array of probe designs to facilitate lavage during laparoscopic surgery. This device has applications in laparoscopic gynecologic, general, thoracic and urology procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.

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)*

Joshua C. Nipper -S

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

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: K141592

1. Submitter information:

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

Address: 2/F, Bldg 31, The 3rd Industrial Area, Mashantou, Gongming Street, Guangming New District, ShenZhen City,Guangdong Province, China

Tel : 0086-755-27111581

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Establishment Registration Number:3010806467

2. Contact person:

Long Yang (COO)

Shenzhen Hlongmed Biotech Co., Ltd.

R1508, East Building, Yihai Plaza, Chuangye Road, Nanshan District,Shenzhen, P.R. China

Tel: 0086-755-86664986

Fax: 0086-755-86664933

E-mail: yanglong@hlongmed.com

3. Identification of the Device :

Trade Name: Unimicro Suction Irrigation Tubing set

Model: Suction Irrigation Tubing Set A, Suction Irrigation Tubing Set B.

Common Name: Suction Irrigation

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 Suction Irrigation Set	Suction Irrigation	Unimax Medical Systems Inc.	Class Ⅱ, GCJ	21CFR 876.1500	K103509

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

The Unimicro Suction Irrigation Tubing set is available with an array of probe designs to facilitate lavage during laparoscopic surgery. This device has applications in laparoscopic gynecologic, general, thoracic and urology procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.

6. Device Description

The Unimicro Suction Irrigation Tubing set is indicated for use in patients undergoing a laparoscopic surgical procedure. It is designed to deliver-sterile irrigation fluids to surgical sites during laparoscopic procedures and to evacuate blood, tissue debris, and smoke from the surgical site.

The suction irrigation set consists of a hand piece equipped with two trumpet style valves, a probe, and connecting lines of tubing, one set designed to attach to a supply of irrigation fluid, and the other designed to attach to an aspiration pump. The valves allow controlled irrigation and aspiration during a surgical procedure.

The hand piece of the suction irrigator is designed to allow instruments to be introduced through the suction irrigation probe to reach the operative site. The instrument adapter is adjustable to allow a variety of instruments and diameters. It is a single use, disposable device and is sold sterile.

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 Unimicro Suction Irrigation Tubing set.

All the test results demonstrate the performance of Unimicro Suction Irrigation Tubing set meets the requirements of its pre-defined acceptance criteria and intended uses.

The results of the non-clinical testing demonstrate that the Unimicro Suction Irrigation Tubing set is as safe and effective as the predicate devices.

8. Substantial Equivalence Determination

The Unimicro Suction Irrigation Tubing set submitted in this 5 10(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared Unimax Suction Irrigation Set which is the subject of K103509.

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	Predicate Device
Trade Name	Unimicro Suction Irrigation Tubing set	Unimax Suction Irrigation Set
510(K) Submitter	Unimicro Medical Systems (ShenZhen) Co.,Ltd.	Unimax Medical Systems Inc.
510(K) Number	----------	K103509
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	This device is available with	This device is available with

Use	an array of probe designs to facilitate lavage during laparoscopic surgery. This device has applications in laparoscopic gynecologic, general, thoracic and urology procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.	an array of probe designs to facilitate lavage during laparoscopic surgery. This device has applications in laparoscopic gynecologic, general, thoracic and urology procedures to provide suction and irrigation functions to help flush blood and tissue debris from the operative site during laparoscopy to aid visualization.
Sterile	Yes	Yes
Disposable	Yes	Yes
Biocompatibility	Cytotoxicity Test; Intracutaneous Reactivity Test; Maximization Sensitization Test;	Cytotoxicity Test; Intracutaneous Reactivity Test; Maximization Sensitization Test;
Specification	The device consists of a hand piece equipped with two trumpet style,valves, a probe, and connecting lines of tubing	The device consists of a hand piece equipped with two trumpet style,valves, a probe, and connecting lines of tubing
Function	The tubing one set designed to attach to a supply of irrigation fluid, and the other designed to attach to an aspiration pump. The valves allow controlled irrigation and aspiration during a surgical procedure.	The tubing one set designed to attach to a supply of irrigation fluid, and the other designed to attach to an aspiration pump. The valves allow controlled irrigation and aspiration during a surgical procedure.

Additional accessories	/	Reusable Monopolar Probe: Description Size: Spatula Probe:5mm×33mm J-Hook Probe:5mm×33mm L-Hook Probe:5mm×33mm

9. Conclusion

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