December 7, 2017

WickiMed(Huizhou)Medical Equipment Manufacturing Co.,Ltd.
Haobin Li
General Manager
TangJiao XingWang Street, Lilin Town
ZhongKai Hi-Tech Zone
Huizhou, GuangDong, China

Re: K172578
Trade/Device Name: Equipment Pouch, Models: WEP010306A, WEP010306B, WEP010507A, WEP010507B
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 15, 2017
Received: November 20, 2017

Dear Haobin Li:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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 below.

510(k) Number *(if known)*

K172578

Device Name

Equipment Pouch, models :WEP010306A, WEP010306B, WEP010507A, WEP010507B

Indications for Use *(Describe)*

The Equipment Pouch is intended for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

WickiMed (Huizhou) Medical Equipment Manufacturing 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: K172578

The date the summary was prepared: November 15,2017

I. Submitter information:

Manufacturer Name: WickiMed (Huizhou) Medical Equipment Manufacturing Co. ,Ltd.

Address: TangJiao XingWang Street, LiLin Town, ZhongKai Hi-Tech Zone, HuiZhou,GuangDong, China.

Tel : 0086-0752-3860807

Fax : 0086-0752-3863017

Establishment Registration Number:3010601992

2. Contact person:

Haobin Li (General Manager)

WickiMed (Huizhou) Medical Equipment Manufacturing Co.,Ltd

TangJiao XingWang Street, LiLin Town, ZhongKai Hi-Tech Zone, HuiZhou, GuangDong, China.

Tel: 0086-0752-3860807

Fax: 0086-0752-3863017

E-mail: mac_lai@wickimed.com

3. Identification of the Device:

Trade Name: Equipment Pouch

Model: WEP010306A, WEP010507A, WEP010306B, WEP010507B

Common Name: Tissue Bags

WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.

Classification Name	Laparoscope, General & Plastic Surgery
Product Code	GCJ
Regulation Number	21 CFR 876.1500
Regulatory Class	II
Review Panel	General & Plastic Surgery

4. Identification of the Predicate Device

Table l: Predicate Device Information

Device Name	Unimicro Disposable Retrieval Endo-Pouch
Common Name	Tissue Bags
Manufacturer	Unimicro Medical Systems (ShenZhen) Co., Ltd.
Classification and Code	Class II, GCJ
Classification regulation	21 CFR 876.1500
510(k) number	K141593

5. Intended Use and Indications for Use

The Equipment Pouch is intended for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.

6. Device Description

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

7. Non-clinical Testing

A series of safety tests were performed to assess the safety and effectiveness of the Equipment Pouch. The safety tests were conducted in accordance with ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-7:2008, ISO 10993-10:2010, ISO 10993-11:2006, ISO 10993-12:2012, and ISO 11135:2014. The test items are Cytotoxicity, Sensitization,

WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.

Intracutaneous reactivity, Acute systemic toxicity and Material-Mediated Pyrogenicity.

The tests listed below demonstrate the performance of Equipment Pouch meets the requirements of its pre-defined acceptance criteria and intended uses.

- Opening force

Demonstrates sufficient smoothness.

- Rope tension test

Equipment Pouch rope can withstand at least 2kg of weight.

- Bag load-bearing

Demonstrates bag body can bear 1Kg weight and keep integrity.

- Tensile strength

Demonstrates adequate weld strength.

- Bag Leak Test

Demonstrates that the Pouch has no leaks.

The Comparative testing results of the non-clinical testing demonstrate that the Equipment Pouch is as safe and effective as the predicate device in performance.

8. Substantial Equivalence Determination

The Equipment Pouch submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, performance to the cleared Unimicro Disposable Retrieval Endo-Pouch which is the subject of K141593. There are no differences between the two devices and no any new issues of safety or effectiveness.

The comparison to predicate device as below Table 2.

WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.

Table 2 : Comparison to Predicate Device

Item	Predicate Device	Proposed Device
Trade Name	Unimicro Disposable Retrieval Endo-Pouch	Equipment Pouch
510(K) Submitter	Unimicro Medical Systems (ShenZhen) Co.,Ltd.	WickiMed(Huizhou)Medical Equipment Manufacturing Co.,Ltd
510(K) Number	K141593	-
Classification regulation	21 CFR 876.1500	21 CFR 876.1500
Classification and Code	ClassⅡ, GCJ	ClassⅡ, GCJ
Device Classification Name	Laparoscope, General & Plastic Surgery	Laparoscope, General & Plastic Surgery
Indications for Use	Indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.	Indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures.
Contraindication	The device is not intended for use when endoscopic techniques are contraindicated	The device is not intended for use when endoscopic techniques are contraindicated
Model	Endo-Pouch With Introducer	WEP010306A; WEP010507A
	Auto Retrieval Endo-Pouch	WEP010306B; WEP010507B
Specification	consists of a flexible	consists of a flexible

WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.

	polymer bag and an introducer structure that fits through a trocar port	polymer bag and an introducer structure that fits through a trocar port
Endo-Pouch Dimension	3"x6" 5"x7"	3"x6" 5"x7"
Patient Contacting Material	PTFE TPU ABS	Nitinol ABS TPU
Safety standards	ISO 10993-1:2003 ISO 10993-5:2009 ISO 10993-7 :2008 ISO 10993-10:2010 ISO 10993-12 :2012 ISO 11135-1 :2007	ISO 10993-1 ISO 10993-5 ISO 10993-7 ISO 10993-10 ISO 10993-11 ISO 10993-12 ISO 11135
Sterilization	EO Sterilized	EO Sterilized
Disposable	Yes	Yes

9. Conclusion

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