March 20, 2023

WickiMed (Huizhou) Medical Equipment Manufacturing Co., Ltd.
Mac Lai
CEO
TangJiao XingWang Street, Lilin Town ZhongKai Hi-Tech Zone
HuiZhou, GuangDong 516003
China

Re: K222828
Trade/Device Name: Specimen Bag, model: WEP040306B, WEP010304B, WEP040304B, WEP010759B, WEP010709B, WEP010304A, WEP010759A, WEP010709A
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 21, 2023
Received: February 21, 2023

Dear Mac Lai:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.03.20 12:22:57 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Specimen Bag：
WEP040306B,WEP010304B,WEP040304B,WEP010304A,WEP010759B,WEP010759A,WEP010709B,WEP010709A

Indications for Use *(Describe)*
The Specimen Bag 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.

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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: K222828

The date the summary was prepared: February 5, 2023

1. 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: Specimen Bag

Model:WEP040306B,WEP010304B,WEP040304B,WEP010304A,WEP010759B,WEP010759A,WEP010709B,WEP010709A

Common Name: Tissue Bags

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

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

4. Identification of the Predicative Device

Predicate Device name:Equipment Pouch

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

510(K) number: K172578

Product Code: GCJ

Classification Names: Laparoscope, General & Plastic Surgery

CFR Reference: 21CFR 876.1500

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

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

7. Non-clinical Testing

A series of safety tests were performed to assess the safety and effectiveness of the Specimen Bag.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, Intracutaneous reactivity,Acute systemic toxicity and Material-Mediated Pyrogenicity.

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

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

- Tensile strength
- Bag load-bearing
- Opening force
- Rope tension test
- Puncture Force Test
- Pouch Leakage Test

The results of the non-clinical testing demonstrate that the Specimen Bag is as safe and effective as the predicate device.

8. Substantial Equivalence Determination

The Specimen Bag submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, performance to the cleared Equipment Pouch which is the subject of K172578. The difference in material has been evaluated for biocompatibility does not raise any safety and effectiveness issues.

The comparison to predicate device as below Table 2.

Table 2 : Comparison to Predicate Device

Item	Predicate Device	Proposed Device
Trade Name	Equipment Pouch	Specimen Bag
510(K) Submitter	WickiMed(Huizhou)Medical Equipment Manufacturing Co.,Ltd	WickiMed(Huizhou)Medical Equipment Manufacturing Co.,Ltd
510(K) Number	K172578	-
Classification regulation	21 CFR 876.1500	21 CFR 876.1500
Classification and Code	Class Ⅱ, GCJ	Class Ⅱ, GCJ

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

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	Memory Type	Memory Type
	Detachable type	Detachable type
Specification	consists of a flexible polymer bag and an introducer structure that fits through a trocar port	consists of a flexible polymer bag and an introducer structure that fits through a trocar port
Endo-Pouch Dimension	3"×6" 5"×7"	3"×4" 3"×6" 7"×9" 7.5"X9"
Patient Contacting Material	Nitinol ABS TPU	Nitinol ABS TPU Nylon composite film
Safety standards	ISO 10993-1 ISO 10993-5 ISO 10993-7	ISO 10993-1 ISO 10993-5 ISO 10993-7

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

	ISO 10993-10 ISO 10993-11 ISO 10993-12 ISO 11135	ISO 10993-10 ISO 10993-11 ISO 10993-12 ISO 11135
Sterilization	EO Sterilized	EO Sterilized
Disposable	Yes	Yes

9. Conclusion

WickiMed(Huizhou)Medical Equipment Manufacturing Co.,Ltd. believes that the Specimen Bag is substantially equivalent to its predicate device (WickiMed Equipment Pouch) K172578 . It has substantially equivalent indications and contraindication , technological characteristics, and performance characteristics to these of the predicate device , and therefore does not introduce any new safety or effectiveness concerns.