June 1, 2020

Hangzhou Jimushi Meditech Co., Ltd.
℅ Wei-Shan Hsu
Regulatory Manager
Vee Care (Asia) Limited
17th Chung Pont Commercial Building, 300 Hennessy Road
Hong Kong
China

Re: K200134
Trade/Device Name: Jimushi Sterile Urethral Catheter for single use
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM
Dated: April 24, 2020
Received: April 24, 2020

Dear Wei-Shan Hsu:

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,

for
Purva Pandya
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200134

Device Name
Jimushi Sterile Urethral Catheter for single use

Indications for Use *(Describe)*
Intermittent urinary catheterization by inserting through the urethra to pass urine from the bladder.

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.

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510(k) Summary

1. Date Prepared

May 27th, 2020

2. Submitter's Information

Name of Sponsor: Hangzhou Jimushi Meditech Co.,Ltd.

Address: 5F, Building 2, No.12 Longtan Road, Cangqian Street, Yuhang District, Hangzhou, Zhejiang, China

Contact Name: Fenlong Wu

Telephone No.: +86-571-85857559

3. Trade Name, Common Name, Classification

Trade Name: Jimushi Sterile Urethral Catheter for single use

Common Name: Catheter, Urethral

Regulation classification name: Urological catheter and accessories

Regulation number: 21 CFR 876.5130

Product code: GBM

Device Class: Class II

4. Identification of Predicate Device(s)

K183461 Teleflex Medical Rusch FloCath Quick Urological Catheter

5. Description of the Device

Jimushi Sterile Urethral Catheter for single use is a disposable sterile catheter intended to be inserted through the urethra to the bladder for urine drainage. The target users are children (greater than 2 years of age), women and men.

This product is supplied in three slightly different forms:

1) Common model (conventional uncoated type)
2) Hydrophilic coated model
3) Hydrophilic coated with water pocket model

The catheter body is made of polyvinyl chloride (PVC) with or without hydrophilic coating. The distal end is either a smooth closed straight or coude tip with two eyelets for efficient drainage. The color-coded funnel shaped connector at the proximal end can be connected to a urine collection container.

The catheter body is sterilized by EO, where the water pocket in some models is pre-sterilized by radiation.

6. Indication for Use

Intermittent urinary catheterization by inserting through the urethra to pass urine from the bladder.

7. Similarities and Differences of the Proposed Devices to the Predicate Devices

The subject device Jimushi Sterile Urethral Catheter for single use is substantially equivalent to the predicate device with respect to the intended use, technology and construction. The differences between the predicate and the subject device are minor and any risks have been mitigated through testing. The below table summarizes the differences between the subject and predicate device.

The subject device is substantially equivalent to the predicate device:

	Subject Device	Predicate Device	Similarities and Differences
Manufacturer	Hangzhou Jimushi Meditech Co.,Ltd.	Teleflex Medical, Inc.	
Trade Name	Jimushi Sterile Urethral Catheter for single use	Rusch FloCath QuickUrological Catheter	
510(k) number	N/A	K183461	--
Device Class	Class II	Class II	Same

Product Code	GBM	GBM	Same
Device classification Name	Urological Catheter and Accessories	Urological Catheter and Accessories	Same
Regulation number	876.5130	876.5130	Same
Indications for Use	Intermittent urinary catheterization by inserting through the urethra to pass urine from the bladder.	Rusch FloCath Quick Urological Catheter is a tubular device that is inserted through the urethra to pass urine from the bladder.	Same
Contraindications	-Acute urethritis -Acute prostatitis -Acute epididymitis -Patients with PVC or Gel allergy -Patients are in menstrual period -Patients have calcareous urolithiasis	-Insurmountable Urethral obstructions -Urethral injuries -Urethral inflammation	Similar
Population	Male, Female and Pediatric	Adult and Pediatric, Male and Female	Same
Size range	8-18 Fr.	6-20 Fr.	Similar The size of the subject device ranges within that of the predicate device.

Overall length	Male: 40cm Female: 20cm Pediatric: 30cm	40 cm	Similar
Shaft	Tubular	Tubular	Same
Shaft Material	PVC	PVC	Same
Coating	Hydrophilic (PVP)	Hydrophilic (PVP)	Same
Tip	Straight and Coude	Nelaton, Olive, or Tiemann tip	Similar
Eyelets	Yes	Yes	Same
Liquid for wetting	Purified water	0.9% Sterile saline solution	Different Both purified water and 0.9% saline are effective for activating hydrophilic coating for a safe, smooth and comfortable catheterization.
Biocompatibility	ISO10993-5 Cytotoxicity ISO 10993-10 Sensitization ISO 10993-10 Skin Irritation	ISO10993-5 Cytotoxicity ISO 10993-10 Sensitization ISO 10993-10 Skin Irritation	Same
Primary Packaging	Paper and film peel back	Paper and film peel back	Same
Single use	Yes	Yes	Same
Sterile	Yes	Yes	Same
Sterilization	Ethylene Oxide * Water pocket is sterilized by gamma radiation in advance	Ethylene Oxide	Both are sterilized to SAL 10^{-6} level.

The basic technological and operating principles are the same for both devices. Both the predicate and subject devices have the same intended use. Both the subject and predicate devices are intended for similar patient populations- male, female and pediatric. Both the subject and predicate devices are disposable, sterile, single patient use devices. As evidenced by comparison Table above, the subject Jimushi Sterile Urethral Catheter for single use is substantially equivalent to the predicate device.

It is reasonable that there are some differences between the subject device and its predicate. The differences between the subject device and its predicate do not affect the safety and effectiveness.

8. Non-clinical Performance Data

The bench testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

Testing Performed	Reference to Standard	Results
Visual Inspection	NA	Pass
Flow Rate	ASTM F623– 99 (Reapproved 2013), EN 1616:1997, ISO 20969:2018	Pass
Product length	ISO 20969:2018	Pass
ID/OD	ASTM F623– 99 (Reapproved 2013), EN 1616:1997	Pass
Eyelets dimensions	NA	Pass
Angle of the coude tip	NA	Pass
Strength	ISO 20969:2018	Pass
Peak tensile force	ISO 20969:2018	Pass
Bending resistance	YY-0325:2016	Pass
Kink stability	ISO 20969:2018	Pass
Connector security	ISO 20969:2018	Pass

Coating appearance and length	NA	Pass
Adhesion of coating	ISO11070:1998	Pass
Lubricity of coating	NA	Pass
Water volume, pressure performance of water pocket	NA	Pass
Water quality of the water pocket	USP23	Pass
Biocompatibility Testing	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2010	Pass
Sterilization	ISO 11135: 2014 ISO 11137-1: 2006	Pass

The subject device was tested to the requirements of EN 1616:1997, ISO 20969:2018 and ASTM F623:2013.

Cytotoxicity, Sensitization and Irritation were performed to demonstrate biocompatibility of the patient contacting materials.

The subject device is sterilized using Ethylene Oxide method and the water pocket is sterilized using Gamma Irradiation method in advance. The respective sterilization validations performed are ETO overkill method and the dose audit study.

Overall, the results are comparable to the predicate and support a determination of substantial equivalence.

9. Conclusion

The Jimushi Sterile Urethral Catheter for single use has the same intended use and technological characteristics as the predicate. Test results demonstrate that the subject devices meet their intended use and performs as well as the legally marketed predicate device. It is for these reasons that the subject device can be found substantially equivalent.