April 5, 2023

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

Re: K222677
Trade/Device Name: Intermittent nelaton catheter for single use
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: March 2, 2023
Received: March 2, 2023

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,

Jessica K. Nguyen -S

Jessica Nguyen
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222677

Device Name
Intermittent nelaton 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.

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

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510(k) Summary

1. Date Prepared

April 4th, 2023

2. Submitter's Information

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

Address: Bldg. 1, No. 12 Longtan Rd., Cangqian St., Yuhang Dist., Hangzhou, Zhejiang Prov., P.R. China

Contact Name: Fenlong Wu

Telephone No.: +86-571-85857559

3. Trade Name, Common Name, Classification

Trade Name: Intermittent nelaton catheter for single use

Common Name: Urethral Catheter

Classification Name: Urological Catheter and Accessories

Regulation Number: 21 CFR 876.5130

Product Code: EZD

Device Class: Class II

4. Identification of Predicate Device(s)

K200134 Jimushi Sterile Urethral Catheter for single use-Hydrophilic coated model

This predicate has not been subject to a design-related recall.

5. Description of the Device

Intermittent nelaton 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. The catheter body is made of polyvinyl chloride (PVC) coated with gel lubricating substance. The distal end is either a smooth closed straight or coude tip and has two eyelets for efficient drainage. The funnel shaped

color-coded connector at the proximal end can be connected to a urine collection container. There is a contact free device, which is for an easy grip, allowing for touchless insertion.

The product is packaged in sealed plastic bags and sterilized with ethylene oxide.

6. Indication for Use

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

7. Model Information

Product code	Specifications (Fr)	Color of the drainage funnel	Total length (L2)/mm	Tip	Population
NCG08M	08	Light blue	405±10	Straight-tip	Male
NCG10M	10	Black	405±10		
NCG12M	12	White	405±10		
NCG14M	14	Green	405±10		
NCG16M	16	Orange	405±10		
NCG18M	18	Red	405±10		
NCG08MC	08	Light blue	405±10	Coude-tip	Male
NCG10MC	10	Black	405±10		
NCG12MC	12	White	405±10		
NCG14MC	14	Green	405±10		
NCG16MC	16	Orange	405±10		
NCG18MC	18	Red	405±10		
NCG08F	08	Light blue	155±10	Straight-tip	Female
NCG10F	10	Black	155±10		
NCG12F	12	White	155±10		
NCG14F	14	Green	155±10		
NCG16F	16	Orange	155±10		
NCG18F	18	Red	155±10		
NCG08P	08	Light blue	255±10	Straight-tip	Pediatric
NCG10P	10	Black	255±10		
NCG12P	12	White	255±10		
NCG14P	14	Green	255±10		
NCG16P	16	Orange	255±10		
NCG18P	18	Red	255±10		

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

The Intermittent nelaton catheter for single use is substantially equivalent to the predicate device, Jimushi Sterile Urethral Catheter for single use (K200134) in that these devices have same intended use and technological characteristics. The basic technological and operating principles are the same for both devices. Both the subject and predicate devices are disposable, sterile, single patient use devices. The differences between the subject device and predicate device do not affect the basic design principle and usage.

A detailed comparison to the predicate is provided in Table 1.

	Subject Device	Predicate Device	Similarities and Differences
Manufacturer	Hangzhou Jimushi Meditech Co.,Ltd.	Hangzhou Jimushi Meditech Co.,Ltd.	
Trade Name	Intermittent nelaton catheter for single use	Jimushi Sterile Urethral Catheter for single use-Hydrophilic coated model	
510(k) number	N/A	K200134	--
Device Class	Class II	Class II	Same
Product Code	EZD	GBM	FDA procode change
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.	Intermittent urinary catheterization by inserting through the urethra to pass urine from the bladder.	Same

<table>
<tr><td>Contraindications</td><td>-Acute urethritis
-Acute prostatitis
-Acute epididymitis
-Patients with PVC or Gel allergy
-Patients are in menstrual period
-Patients have calcareous urolithiasis</td><td>-Acute urethritis
-Acute prostatitis
-Acute epididymitis
-Patients with PVC or Gel allergy
-Patients are in menstrual period
-Patients have calcareous urolithiasis</td><td>Same</td></tr>
<tr><td>Population</td><td>Male, Female and Pediatric</td><td>Male, Female and Pediatric</td><td>Same</td></tr>
<tr><td>Size range</td><td>8-18 Fr.</td><td>8-18 Fr.</td><td>Same</td></tr>
<tr><td>Effective shaft length</td><td><table><tr><th>Fr</th><th>Effective length (mm)</th></tr><tr><td>08
10</td><td>Male,Straight:343±10
Male, Coude: 337±10
Female:96±10
Pediatric: 196±10</td></tr><tr><td>12
14
16
18</td><td>Male,Straight: 337±10
Male, Coude: 333±10
Female:92±10
Pediatric: 192±10</td></tr></table></td><td><table><tr><th>Fr</th><th>Effective length (mm)</th></tr><tr><td>08
10</td><td>Male,Straight:343±3
Male, Coude: 337±3
Female:141±3
Pediatric: 241±3</td></tr><tr><td>12
14
16
18</td><td>Male,Straight: 337±3
Male, Coude: 333±3
Female:137±3
Pediatric: 237±3</td></tr></table></td><td>Different [1]</td></tr>
<tr><td>Shaft</td><td>Tubular</td><td>Tubular</td><td>Same</td></tr>
<tr><td>Shaft Material</td><td>PVC</td><td>PVC</td><td>Same</td></tr>
<tr><td>Coating</td><td>Gel (glycerin, polyacrylic acid, propylene glycol, sodium polyacrylate)</td><td>Hydrophilic (PVP)</td><td>Different [2]</td></tr>
<tr><td>Tip</td><td>Straight and Coude</td><td>Straight and Coude</td><td>Same</td></tr>
<tr><td>Eyelets</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
</table>

Biocompatibility	ISO10993-5 Cytotoxicity ISO 10993-10 Sensitization ISO 10993-23 Penile irritation ISO 10993-11:2017 Subchronic systemic toxicity test	ISO10993-5 Cytotoxicity ISO 10993-10 Sensitization ISO 10993-10 Penile irritation	Different [3]
Primary Packaging	PE+PET film/ XPP-R film	Dialysis paper and plastic film	Different [4]
Single use	Yes	Yes	Same
Sterile	Yes	Yes	Same
Sterilization	Ethylene Oxide	Ethylene Oxide	Same

9. Justification for the differences

(1) Different effective shaft length

The subject device has shorter effective shaft length for female and pediatrics than predicate device. The effective shaft length of subject device fulfills the requirement of ISO 20696:2018. This difference does not affect the substantial equivalence of the device.

(2) Different coating material

The coating material of subject device and predicate device is different. Biocompatibility tests were conducted to demonstrate substantial equivalence of the subject device.

(3) Different ISO 10993 standard for irritation test and addition of subchronic systemic toxicity test

The penile irritation of the subject device complies to new standard ISO 10993-23:2021, which is specific for irritation testing instead of ISO 10993-10:2010. This difference does not affect the substantial equivalence of the device.

As this product is considered to be a device with prolonged contact-

duration given the repeated use, subchronic systemic toxicity test was conducted to validate the biocompatibility.

(4) Different packaging material

The packaging material of subject device and predicate device is different. Packaging integrity testing was conducted to demonstrate the substantial equivalence of the subject device.

10. 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
Product length	ISO 20696:2018	Pass
ID/OD	ASTM F623−19, EN 1616:1997	Pass
Eyelets dimensions	N/A	Pass
Drainage Funnel Connector separation force	ISO 20696:2018	Pass
Peak tensile force	ISO 20696:2018	Pass
Flow Rate	ASTM F623− 19, EN 1616:1997, ISO 20696:2018	Pass
Bending resistance	YY-0325:2016	Pass
Kink stability	ISO 20696:2018	Pass
Lubricity of coating	N/A	Pass
Gel appearance	N/A	Pass
Biocompatibility Testing	ISO 10993-1:2009 ISO 10993-5:2009 ISO 10993-10:2021 ISO 10993-23:2021 ISO 10993-7:2008	Pass
Sterilization	ISO 11135: 2014	Pass

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

11. Conclusion

The Intermittent nelaton catheter for single use has the same intended use and technological characteristics as the predicate. Both the subject and predicate devices are intended for same patient populations- male, female and pediatric. Both the subject and predicate devices are disposable, sterile, single patient use devices.

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. In conclusion, the Intermittent nelaton catheter for single use is substantially equivalent to the predicate device.