June 24, 2026

Hangzhou Jimushi Meditech Co., Ltd.
% Wei-Shan Hsu
Regulatory Manager
Vee Care Asia Limited
9f-25, # 188, Sec. 4, Chenggong Rd., Neihu Dist.,
Taipei, 114049
TAIWAN

Re: K260394
Trade/Device Name: Hydrophilic coated intermittent nalaton catheter for single use-ready to use (NCR)
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: May 22, 2026
Received: May 22, 2026

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 (the 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 available 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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260394

Please provide the device trade name(s).

Hydrophilic coated intermittent nalaton catheter for single use-ready to use (NCR)

Please provide your Indications for Use below.

Intermittent urinary catheterization of adult males, females and pediatrics by inserting through the urethra to pass urine from the bladder.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K260394 510(k) Summary

1. Date Prepared

June 24, 2026

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: Hydrophilic coated intermittent nalaton catheter for single use-ready to use

Regulation 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 with water pocket model

5. Description of the Device

Hydrophilic-coated intermittent catheters for single use-ready to use, is a disposable sterile catheter intended for insertion through the urethra to the bladder for urine drainage. The target users are children (older than 2 years), women, and men.

The catheter body is made of polyvinyl chloride (PVC) with hydrophilic coating. The distal end may have a straight tip, coude tip, or soft tip, and includes two eyelets for efficient drainage. At the proximal end, there is a funnel-shaped, color-coded connector that can be attached to a urine collection container. The

package is prefilled with purified water and with a touch-free sleeve for easy grip, enabling touchless insertion.

The product is packaged in aluminum foil and sterilized by Gamma radiation.

6. Indication for Use

Intermittent urinary catheterization of adult males, females and pediatrics by inserting through the urethra to pass urine from the bladder.

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

The Hydrophilic coated intermittent nalaton catheter for single use-ready to 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	Hydrophilic coated intermittent nalaton catheter for single use-ready to use	Jimushi Sterile Urethral Catheter for single use-Hydrophilic coated with water pocket model	
510(k) number	N/A	K200134	--
Device Class	Class II	Class II	Same
Product Code	EZD	GBM	FDA product code 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 of adult males, females and pediatrics 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
Contraindications	-Acute urethritis -Acute prostatitis -Acute epididymitis -Patients with PVC or Gel allergy -Patients are in menstrual period -Patients have calcareous urolithiasis	-Acute urethritis -Acute prostatitis -Acute epididymitis -Patients with PVC or Gel allergy -Patients are in menstrual period -Patients have calcareous urolithiasis	Same
Population	Male, Female and Pediatric	Male, Female and Pediatric	Same
Size range	8-18 Fr.	8-18 Fr.	Same

<table>
<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±15
Male, Coude: 337±15
Male, Soft tip: 330±15
Female,Straight:96±15
Female, Soft tip: 95±15
Pediatric, Straight: 196±15
Pediatric,Coude:192±15
Pediatric, Soft tip: 195±15</td></tr>
<tr><td>12
14
16
18</td><td>Male,Straight: 337±15
Male, Coude: 333±15
Male, Soft tip: 330±15
Female,Straight:92±15
Female, Soft tip: 95±15
Pediatric,Straight: 192±15
Pediatric,Coude:190±15
Pediatric, Soft tip: 195±15</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>Hydrophilic (PVP)</td><td>Hydrophilic (PVP)</td><td>Same</td></tr>
<tr><td>Tip</td><td>Straight, Coude and Soft-tip</td><td>Straight and Coude</td><td>Different[2]</td></tr>
<tr><td>Eyelets</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Biocompatibility</td><td>ISO10993-5 Cytotoxicity
ISO 10993-10 Sensitization
ISO 10993-10 Penile irritation
ISO 10993-11 Acute systemic Toxicity,</td><td>ISO10993-5 Cytotoxicity
ISO 10993-10 Sensitization
ISO 10993-10 Penile irritation</td><td>Different[3]</td></tr>
</table>

	Subchronic systemic Toxicity, pyrogen test ISO 10993-6 Implantation test ISO 10993-3 Bacterial Reverse Mutation Assay, Chromosome Aberration Assay		
Primary Packaging	Aluminum foil	Dialysis paper and plastic film	Different [4]
Single use	Yes	Yes	Same
Sterile	Yes	Yes	Same
Sterilization	Gamma irradiation	Ethylene Oxide	Different[5]

8. Justification for the differences

According to the comparison table, the subject device when compared to the predicate device differs in the effective shaft length, additional tip configuration, sterile barrier packaging material and the sterilization method. To address differences, non-clinical testing was conducted to support the substantial equivalence of the subject device.

9. 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
ID and OD	ISO 20696:2018	Pass
Eyelets dimensions	NA	Pass
Product length	ISO 20696:2018	Pass
Strength	ISO 20696:2018	Pass
Peak tensile force	ISO 20696:2018	Pass

Air tightness	N/A	Pass
Flow Rate	ISO 20696:2018	Pass
Bending resistance	YY-0325:2022	Pass
Connector security	ISO 20696:2018	Pass
Adhesion of coating	ISO 11070:1998	Pass
Lubricity of coating	N/A	Pass
Water volume	N/A	Pass
Performance and Dimensions of the double-sided adhesive	N/A	Pass
Anti-kinking performance	ISO 20696:2018	Pass
Coating appearance	N/A	Pass
Coating length	N/A	Pass
Sealing edge width	EN868-5:2009	Pass
Seal Strength	EN868-5:2009	Pass
Budding test	ASTM F2096-11	Pass
Biocompatibility Testing	ISO 10993-5:2009 ISO 10993-10:2021 ISO 10993-11:2017 ISO 10993-23:2021 ISO 10993-6:2016 ISO 10993-3:2014	Pass
Sterilization	ISO 11137-2:2013/Amd.1 2022	Pass

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

10. Conclusion

The Hydrophilic coated intermittent nalaton catheter for single use-ready to use has the same intended use and similar 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 predicate device has not been subject to a design-related recall.

The differences in technological characteristics between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. We concluded that Hydrophilic coated intermittent nalaton catheter for single use-ready to use is substantially equivalent to the predicate device.