June 26, 2025

Chengdu Daxan Innovative Medical Tech. Co., Ltd
% Boyle Wang
Manager
Shanghai Truthful Information Technology Co., Ltd.
Room 1801, No. 161 East Lujiazui Rd., Pudong
Shanghai, 200120
CHINA

Re: K243175
Trade/Device Name: Disposable Intermittent Catheter (TPU Catheter)
Regulation Number: 21 CFR 876.5130
Regulation Name: Catheter, Straight
Regulatory Class: II
Product Code: EZD
Dated: May 23, 2025
Received: May 23, 2025

Dear Boyle Wang:

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: 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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243175

Device Name

Disposable Intermittent Catheter (TPU Catheter)

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

K243175

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's information

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Date of Preparation: June 26, 2025

Designated Submission Correspondent

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2.0 Device information

Trade name:	Disposable Intermittent Catheter (TPU Catheter)
Common name:	Catheter, Straight
Classification name:	Urological catheter and accessories

3.0 Classification

Product code:	EZD
Regulation number:	21 CFR 876.5130
Classification:	Class II
Panel:	Gastroenterology/Urology

4.0 Predicate device information

Predicate device:	Jimushi Sterile Urethral Catheter for single use
Manufacturer:	Hangzhou Jimushi Meditech Co., Ltd.
510(k) number:	K200134

The predicate device has not been subject of a design related recall.

5.0 Indication for Use Statement

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

6.0 Device description

The subject device is intended used for drainage of the urinary system, sterile and for single use. Duration of use ≤ 24 hours.
The target populations are children (greater than 2 years of age), adolescents, women and men.
The subject device is supplied in four forms:

Uncoated type	Pediatric male uncoated type, Pediatric female uncoated type, Male uncoated type, Female uncoated type, Bending head uncoated type
Normal type	Pediatric male normal type, Pediatric female normal type, Male normal type, Female normal type, Bending head normal type
Water sachet type	Pediatric male water sachet type, Pediatric female water sachet type, Male water sachet type, Female water sachet type, Bending head water sachet type
Ready-to-use type	Pediatric male ready-to-use type, Pediatric female ready-to-use type, Male ready-to-use type, Female ready-to-use type, Bending head ready-to-use type

The Disposable Intermittent Catheter is made from the TPU, and the hydrophilic coating (optional). The surface hydrophilic coating is made from polyvinyl pyrrolidone. The free contact sleeve is optional.
The Uncoated type catheter is uncoated without other accessories.
The Normal type catheter is coated without other accessories.
The Water sachet type catheter is coated with a sterile water sachet.
The Ready-to-use type catheter is coated and packed in an aluminum-plastic or plastic bag with a small amount of physiological saline.

Environment of use: In medical institutions, used by the trained medical staffs or experienced patients.

7.0 Technological Characteristic Comparison Table

The subject device Disposable Intermittent TPU Catheter 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 differences in technological characteristics do not raise different questions of safety and effectiveness The below table summarizes the differences between the subject and predicate device.

Table 1 - Substantial Equivalence Table

Item	Subject device	Predicate device K200134	Remark
Product Code	EZD	GBM	Similar
Classification name	Urological catheter and accessories	Urological catheter and accessories	Same
Regulation No.	21 CFR 876.5130	21 CFR 876.5130	Same
Class	Class II	Class II	Same
Product name	Disposable Intermittent Catheter (TPU Catheter)	Jimushi Sterile Urethral Catheter for single use	/
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
Condition of Use	Intermittent use and single use	Intermittent use and single use	Same
Population	Adult and Pediatric, Male and Female	Adult and Pediatric, Male and Female	Same
Type	Uncoated type, Normal type (Coated type), Water sachet type, Ready-to-use type	1) Common model (conventional uncoated type), 2) Hydrophilic coated model, 3) Hydrophilic coated with water pocket model	Same
Size range	Pediatric male (6Fr, 8Fr, 10Fr, 12Fr). Pediatric female (6Fr, 8Fr, 10Fr, 12Fr). Male (8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr). Female (8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr)	8-18 Fr	Similar The sizes of the subject device are representative of similar, legally marketed devices.

	Bending head (8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr).		
Overall length	Pediatric male: ⩾20cm Pediatric female: ⩾ 10cm Male: ⩾36cm Female: ⩾15cm Bending head: ⩾36cm	Male: 40cm Female: 20cm Pediatric: 30cm	Similar
Tube Material	TPU (Thermoplastic polyurethanes)	PVC	Different Biocompatibility evaluation has been carried out per ISO 10993-1. There are no new safety and effectiveness concern due to the difference.
Coating	Hydrophilic (PVP) (for the coated type)	Hydrophilic (PVP)	Same
Tip	Straight and Coude	Straight and Coude	Same
Eyelets	yes	yes	Same
Liquid for wetting	Sterile water or physiological saline for Normal type Catheter. Ready-to-use type catheter is coated and packed in an aluminum-plastic or plastic bag with a small amount of physiological saline.	Purified water	Same Sterile water is for wetting the coated type. Physiological saline is packed in the ready-to-use type.
Primary Packaging	Peel pack	Paper and film peel back	Same
Sterile	yes	yes	Same
Sterilization	SAL 10^{-6} Radiation Radiation sterilization dose is 18.7-30.0kGy.	SAL 10^{-6} Ethylene Oxide * Water pocket is sterilized by gamma radiation in advance	Different The sterilization level is the same, but the sterilization method is different. Testing was conducted to support the sterilization process.

Shelf life	3 years	Unknown	Different Accelerated aging was completed to validate the different shelf life.
Materials contacting user	Tube Material: TPU (Thermoplastic polyurethanes) Coating: Hydrophilic (PVP) (for the coated type) Free contact sleeve (optional): LDPE (Low-density polyethylene)	Tube Material: PVC Coating: Hydrophilic (PVP)	Different Biocompatibility evaluation has been carried out per ISO 10993-1. There are no new safety and effectiveness concern due to the difference.

8.0 Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent to the predicate device. The test results demonstrated that the proposed device met the requirements and complies with the following standards:

- ISO 20696 First edition 2018-06; Corrected 2019-12 Sterile urethral catheters for single use
- ISO 11137-1 First edition 2006-04-15 Sterilization of health care products – Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2018)]
- ISO 11137-2 Third edition 2013-06 [Including AMD1:2022] Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose [Including Amendment 1 (2022)]
- ISO 11737-1 Third edition 2018-01 [Including AMD1:2021] Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product [Including Amendment 1 (2021)]
- ISO 11737-2 Third edition 2019-12 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ASTM F88/F88M-21 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F1140/F1140M-13 (Reapproved 2020) e1 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages

- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 8295:1995 Plastics – Film and sheeting – Determination of the coefficients of friction
- ISO 13868:2002 Catheters – Test methods for kinking of single lumen catheters and medical tubing
- Leak resistance testing

Biocompatibility assessments were conducted in accordance with ISO 10993-1: 2018, including:

- Cytotoxicity per ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity.
- Skin Sensitization per ISO 10993-10:2021 Biological Evaluation of Medical Devices - Part 10: Tests For Skin Sensitization.
- Intracutaneous Reactivity Test per ISO 10993-23:2021 Biological Evaluation of Medical Devices - Part 23: Tests For Irritation.
- Acute Systemic Toxicity Test per ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- Sub-Acute Systemic Toxicity Test per ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

All tests met the pre-determined acceptance criteria.

9.0 Conclusion

The conclusions drawn from the performance testing demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, K200134. Accordingly, the subject device is substantially equivalent to the predicate device.