December 7, 2022

Chengdu Daxan Innovative Medical Tech. Co., Ltd
Kevin Huang
RA Manager
Unit 6, Building 1, No.18, North Bayi Road, Wenjiang District
Chengdu, Sichuan 611135
China

Re: K212567
Trade/Device Name: PVC Hydrophilic Urethral Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: November 17, 2022
Received: November 22, 2022

Dear Kevin Huang:

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,

Angel A. Soler-garcia -S

for
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

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)*
K212567

Device Name
PVC Hydrophilic Urethral Catheter

Indications for Use *(Describe)*
The PVC Hydrophilic Urethral Catheter is launched for clean intermittent catheterization -CIC treatment and indicated for use by patients with chronic urine retention. The catheter is inserted into the bladder through the urethra for emptying 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

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	2022/11/16
Submitter:	Chengdu Daxan Innovative Medical Tech. Co.,Ltd Unit 6, Building 1, No.18, North Bayi Road, Wenjiang District, 611135 Chengdu, Sichuan Province, China
Contact Person:	Kevin huang Regulatory Affairs Manager Chengdu Daxan Innovative Medical Tech. Co.,Ltd Email: kevin_huang1021@sina.com Tel: +86-760-22819569 Fax: +86-760-22819569
Trade or Proprietary Name:	PVC Hydrophilic Urethral Catheter
Common or Usual Name:	Catheter, Straight
Regulation Number:	21 CFR 876.5130
Classification Name:	Urological Catheters and Accessories
Product Code:	EZD
Device Classification:	Class Ⅱ
Review Panel:	Gastroenterology-Urology
Predicate Device(s):	K062444 - Hi-Slip Plus Hydrophilic Urethral Catheter

1. Intended Use

The PVC Hydrophilic Urethral Catheter is launched for clean intermittent catheterization -CIC treatment and indicated for use by patients with chronic urine retention. The catheter is inserted into the bladder through the urethra for emptying the bladder.

2. Device Description

The PVC Hydrophilic Urethral Catheter is a single use urinary catheter designed for clean intermittent catheterization, drainage of bladder. The device consists of disposable PVC (medical grade) catheter coated with hydrophilic polymer with/without water sachet (pure water). The catheters are coated with a coating containing polyvinyl pyrrolidone (PVP) - a kind of hydrophilic polymer, which binds the water molecules to the surface of the catheter to reduce the risk of friction while inserting the catheter into the urethra. Coating is activated by the water by squeezing the water sachet or purified water. When the catheter

is immersed in water for 30 seconds, it becomes slippery and ready to use.
The PVC Hydrophilic Urethral Catheter is supplied in French size ranging from 8 to 18. It is available for male and female.

3. Substantial Equivalence—Comparison to Predicate Devices
The PVC Hydrophilic Urethral Catheter is similar to the predicate Hi-Slip Plus Hydrophilic Urethral Catheter K06244. The similar indications for use and technological characteristics of the PVC Hydrophilic Urethral Catheter as compared to the predicate device support a determination of substantial equivalency.

Similarities Between Proposed and Predicate Device
The proposed PVC Hydrophilic Urethral Catheter and the predicate device, K062444 - Hi-Slip Plus Hydrophilic Urethral Catheter, have the similar intended use, principle of operation, performance characteristics and scientific technology.

Differences Between Proposed and Predicate Device
There is no difference between the proposed and the predicate devices.

Therefore, the proposed PVC Hydrophilic Urethral Catheter are substantially equivalent to the K062444 - Hi-Slip Plus Hydrophilic Urethral Catheter. The proposed device has the same classification information, similar intended use and technological characteristics as compared to the predicate devices.

4. Summary of Non-Clinical Performance Testing
The following performance testing was conducted for the PVC Hydrophilic Urethral Catheter:
1) General performance testing including:
- Analysis of Flow rate
- Analysis of strength of the catheter
- Analysis of Connector Security
- Analysis of Coefficients of friction

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for use as a urethral catheter.

Testing data and results are included in this submission, and demonstrated that the PVC Hydrophilic Urethral Catheter meets all the pre-determined testing and acceptance criteria.

2) Bio-compatibility testing as per ISO 10993-1:2009 including:
- Cytotoxicity as per ISO 10993-5:2009

- Irritation as per ISO 10993-10:2010
- Sensitization as per ISO 10993-10:2010
- Subacute toxicity as per ISO 10993-11:2017

Bio-compatibility testing reports are included in this submission, and demonstrated that the device components that are in contact with the patient are bio-compatible.

Conclusions Drawn from the Non-Clinical Testing

The results of these tests demonstrate that the device is as safe, as effective, and performs as well as the identified predicates and support a determination of substantial equivalence.

5. Conclusion

The PVC Hydrophilic Urethral Catheter is substantially equivalent to predicate devices K062444 - Hi-Slip Plus Hydrophilic Urethral Catheter. Based on the intended use, principle of operation, performance characteristics, and technological characteristics, the proposed PVC Hydrophilic Urethral Catheter is substantially equivalent to and as safe, as effective and performs as the legally marketed predicate devices.