June 16, 2025

Guangdong Ecan Medical Co., Ltd.
Summer Wang
RA Engineer
Building 1, No. 222, Xindu Road, Chengjiao Street,
Conghua District
Guangzhou, Guangdong 510920
CHINA

Re: K243011
Trade/Device Name: Silicone Urethral Catheter (Silicone Urethral Catheter)
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: May 23, 2025
Received: May 23, 2025

Dear Summer 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,
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243011

Device Name
Silicone Urethral Catheter

Indications for Use *(Describe)*
The Silicone Urethral Catheter is passed through the urethra during urinary catheterization and into the bladder to drain urine, or for routine post-operative drainage and bladder irrigation. It is intended for use by male, female and pediatric patients (2 years old to less than 12 years old).

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date of Preparation: May 23, 2025

1. **Applicant:**
510(k) Owner's Name: Guangdong Ecan Medical Co., Ltd.
Address: Building 1, No. 222, Xindu Road, Chengjiao Street, Conghua District, Guangzhou City, Guangdong Province, 510920, P.R. China
Contact Person: Liuyuan Han
Title: General Manager
Email: hanliuyuan@ecanmed.com
Tel: +86 020-37501359
Fax: +86 020-37501359

2. **Submission Correspondent:**
Contact Person: Summer Wang
Email: 1135770505@qq.com
Tel: +86-20-84558599
Fax: +86-20-84558599

3. **Device Information**
Device Name: Silicone Urethral Catheter
Common Name: Urethral Catheter, Foley Catheter
Regulation Number: 21 CFR 876.5130
Classification Name: Urological Catheter and Accessories
Review Panel: Gastroenterology/Urology
Classification: II
Product Code: EZL

4. **Predicate and Reference Device Identification**
Predicate: K233094 — Wellead® Latex Foley Catheter
Predicate device was not subjected to any design related recall.

5. Indications for Use

The Silicone Urethral Catheter is passed through the urethra during urinary catheterization and into the bladder to drain urine, or for routine post-operative drainage and bladder irrigation. It is intended for use by male, female and pediatric patients (2 years old to less than 12 years old).

6. Device Description

The Silicone Urethral Catheter is inserted through the urethra during urinary catheterization and goes into the bladder for urine drainage or irrigation. It consists of shaft, drainage funnel,

inflation funnel, irrigation funnel (if present), balloon and valve. The balloon of the catheter can be inflated and fixed the catheter in place after being injected with a sterile liquid.
The device is made of silicone and available in different types (e.g., male, female, Tiemann, 2-way, 3-way etc.) and sizes for adult and pediatric use.
The device is for single use and provided with sterile. The indwelling time is no more than 30 days.

Table of Variants

Type	Size
2-way Pediatric	6Fr, 8 Fr, 10 Fr
2-way Female	12Fr, 14 Fr, 16 Fr, 18 Fr, 20 Fr, 22 Fr, 24 Fr
2-way Male (Standard)	12Fr, 14 Fr, 16 Fr, 18 Fr, 20 Fr, 22 Fr, 24 Fr
2-way Tiemann	16 Fr, 18 Fr, 20 Fr, 22 Fr, 24 Fr
3-way Male (Standard)	16 Fr, 18 Fr, 20 Fr, 22 Fr, 24 Fr

7. Substantial Equivalence—Comparison to Predicate Devices

A side by side comparison of the proposed device and the predicate device are provided below.

Table 1 - Comparison Table

Comparison between proposed device and predicate device			
Comparison Items	**Proposed Device**	**Predicate Device**	**Discussion of Differences**
Device Name	Silicone Urethral Catheter	Wellead® Latex Foley Catheter	---
510k Number	---	K233094	---
Product Code	EZL	EZL	Same
Regulation Number	21 CFR 876.5130	21 CFR 876.5130	Same
Regulatory Class	Class Ⅱ	Class Ⅱ	Same
Classification Name	Urological Catheter and Accessories	Urological Catheter and Accessories	Same
Indications for Use	The Silicone Urethral Catheter is passed through the urethra during urinary catheterization and into the bladder to drain urine, or for routine post-operative drainage and bladder irrigation. It is intended for use by male, female and pediatric patients (2 years old to less than 12 years old).	Latex Foley Catheter is inserted into the bladder through urethra and are indicated for routine urine drainage or for routine post-operative drainage and bladder irrigation.	Same. Both of them are intended to be inserted through the urethra to the bladder for urine drainage.
Patient Population	Pediatric, Male and Female	Pediatric, Male and Female	Same
Device Type (Lumen)	2-way 3-way	2-way 3-way	Same
Patient Contact Materials	Shaft: Silicone Tip: Silicone Balloon: Silicone	Shaft: Latex(silicone coated) Tip: Latex Balloon: Latex	※ Differernt
Catheter French Size (Fr)	2-way: 6-24Fr 3-way: 16-24Fr	6-30Fr	Same. The proposed device's sizes are included within the size range of the predicate device.
Balloon	2-way: Yes	2-way: Yes	Same

	3-way: Yes	3-way: Yes	
Balloon Volume	3mL 3-5mL 5mL 5-10mL 10mL 5-15mL 15-20mL 20-30mL 20mL 30mL	3mL 3-5mL 5mL 5-10mL 10mL 5-15mL 15mL 15-30mL 20mL 30mL	Same. The proposed device's balloon volumes are included within the range of the predicate device.
Tip Shape	Straight round and Tiemann (Coude tip)	Straight and Coude	Same
Stylet in Pediatric Type	Yes (for pediatric sizes) Not for adult sizes	Yes (for pediatric sizes) Not for adult sizes	Same
Duration of Use	Less than 30 days	less than 30 days	Same
Use Environment	Health care facilities	Health care facilities	Same
Target Population	Pediatric, Male and Female	Pediatric, Male and Female	Same
Sterilization Method	EtO Sterilized	EtO Sterilized	Same
Packaging	Peel pack comprises paper and film; Corrugated board outer case.	Peel pack comprises paper and film; Corrugated board outer case.	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Prescription Use	Yes	Yes	Same
Biocompatibility	Cytotoxicity Sensitization Irritation (intracutaneous reactivity) Acute systemic toxicity Subacute toxicity Implantation effects Pyrogenicity Conforms to ISO 10993-1	Conforms to ISO 10993-1	Same

Similarities Between Proposed and Predicate Device

The proposed Silicone Urethral Catheters have the same technological characteristics as the predicate device (K233094 — Wellead® Latex Foley Catheter). The proposed and predicate device are based on the following same technological elements:

- Same intended use
- Same Indications for Use
- Same operating principals
- Same patient population
- Same Environment of Use
- Composed of biocompatible materials
- Provided sterile for single-use
- Ethylene Oxide Sterilized

Differences Between Proposed and Predicate Device

※ **Materials**

The proposed device is made from Silicone material while the predicate device is made from Latex (silicone coated). Although the materials are not identical, but they both are

manufactured from materials that meet all the requirements of biocompatibility, the materials in contact were tested as per ISO 10993-1.
Therefore, the material difference does not raise different questions of safety and effectiveness than the predicate device.

As evidenced by the above table, both the proposed and the predicate device have same Indications for Use and technological characteristics. The minor difference in the device does not introduce new issues of safety and efficacy.
Therefore, the proposed Silicone Urethral Catheter is substantially equivalent to the predicate device (K233094 — Wellead® Latex Foley Catheter). The proposed device has the same classification information, same indications for use and technological characteristics as compared to the predicate device.

8. Summary of Non-Clinical Performance Testing

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was same to the predicate device.
Device performance data was provided in support of the substantial equivalence determination.

1) Bench Testing

The following bench performance testing were conducted per ASTM F623-19, ISO 20696:2018 and the FDA guidance document, '*Conventional Foley Catheters - Performance Criteria for Safety and Performance Based Pathway'.*

※ Balloon Size and Shaft Size
※ Flow Rate
※ Balloon Integrity (Resistance to Rupture)
※ Inflated Balloon Response to Traction
※ Balloon Volume Maintenance
※ Deflation Reliability (Failure to Deflate)
※ Surface Finish (Appearance)
※ Dimensions
※ Strength
※ Connector Security
※ Balloon safety
※ Corrosion resistance
※ Kink stability
※ Peak Tensile Force
※ Stylet Pull-out Force

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

2) Biocompatibility

Biocompatibility testing was conducted based upon ISO 10993-1 (2018): Biological evaluation of medical devices – Part 1: "Evaluation and testing within a risk management process" and FDA Guidance document (2023), *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management*

process" FDA". The Silicone Urethral Catheter is surface device in contact with mucosal tissue for prolonged exposure (＞24 h to 30 d) and following tests were conducted in accordance with the relevant ISO 10993 standards:

- Cytotoxicity
- Intracutaneous
- Skin Sensitization
- Acute Systemic Toxicity
- Subacute Toxicity
- Implantation
- Pyrogenicity

Biocompatibility testing reports are included in this submission, and demonstrated that the device components that are in contact with the patient are biocompatible. All evaluation acceptance criteria were met.

3) Sterilization and Shelf-Life

The Silicone Urethral Catheter was validated to be sterilized using ethylene oxide in accordance with ISO 11135:2014.

To support the claimed shelf life, the Silicone Urethral Catheter was subjected to bench performance testing, transportation testing and package integrity testing to demonstrate that the product and package would be undamaged throughout the product life and maintain device sterility.

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 predicate and support a determination of substantial equivalence.

9. Clinical Testing and animal testing

Clinical and animal testing were not performed for Silicone Urethral Catheter as part of the premarket Notification requirements for this 510(k) submission and the subject of this premarket submission, Silicone Urethral Catheter, did not require clinical and animal studies to support substantial equivalence.

10. Conclusion

Based on the information presented in this submission, it can be concluded that the proposed device Silicone Urethral Catheter is substantially equivalent to the predicate device (K233094 — Wellead® Latex Foley Catheter).