December 16, 2022

Well Lead Medical Co., Ltd.
Jenny Zhu
RA Supervisor
No.47, Guomao Avenue South, Hualong, Panyu
Guangzhou, 511434
China

Re: K220036
Trade/Device Name: Wellead® Ureteral Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: KOD
Dated: November 11, 2022
Received: November 14, 2022

Dear Jenny Zhu:

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 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
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220036

Device Name
Wellead® Ureteral Catheter

Indications for Use *(Describe)*
The Ureteral Catheter is used for temporary urine drainage, delivery of irrigation fluids, injection of contrast agent to the urinary tract, navigation of a tortuous ureter, access, advancement or exchange of wire guides (open-ended catheters only).

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

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

1. Submitter's Information

- 510(k) Owner's Name: Well Lead Medical Co., Ltd.
- Address: No.47, Guomao Avenue South, Hualong, Panyu, Guangzhou, China 511434
- Tel: 86 20 8475 8878-8029
- Contact Person (including title): Ms. Jenny Zhu (RA Supervisor)
- E-mail: jenny_zhu@welllead.com.cn

2. Subject Device Information

- Type of 510(k) submission: Traditional
- Common Name: Ureteral Catheter
- Trade Name: Wellead® Ureteral Catheter
- Device: Catheter, Urological
- Regulation Name: Urological catheter and accessories
- Regulation Medical Specialty: Gastroenterology/Urology
- Review Panel: Gastroenterology/Urology
- Product Code: KOD
- Regulation Number: 876.5130
- Regulation Class: 2

3. Predicate Device Information

Predicate Device

Sponsor	Cook Incorporated
Device Name	Open-End Ureteral Catheter, Open-End Ureteral Catheter Sof-Flex, EchoTip Open-End Ureteral Catheter, Open-End Flexi-Tip Ureteral Catheter, Flexi-Tip Ureteral Catheter (Closed End), Whistle Tip Ureteral Catheter, Round Tip Ureteral Catheter, Spiral Tip Ureteral Access Catheter, Pediatric Ureteral Catheter
510(k) Number	K171662
Product Code	KOD
Regulation Number	876.5130
Regulation Class	2

There are no design related recalls for this predicate.

4. Device Description

Ureteral Catheters are single-use and sterile devices, which consist of catheter, adapter and guide wire. Ureteral Catheters are available in a variety of French sizes and distal tip configurations. Ureteral Catheters have 5 different distal tip configurations, which are closed round tip, open tapered tip, open tip, open soft tip and open cone tip. The adapter and guide wire are optional and the choice of Ureteral Catheter, adapter and guide wire should be based on the physician's preference and clinical situation.

The catheter tube is made of Polyvinylchloride (PVC). The catheter is uncoated.

Recommend duration of use: less than 24 hours.

5. Indications for Use

The Ureteral Catheter is used for temporary urine drainage, delivery of irrigation fluids, injection of contrast agent to the urinary tract, navigation of a tortuous ureter, access, advancement or exchange of wire guides (open-ended catheters only).

6. Test Summary

Ureteral Catheter has been evaluated the safety and performance by lab bench testing as following:

- ASTM F1929 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1886 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
- ISO 80369-20: 2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods
- ISO 10993-1:2018 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- ASTM F640-20 Standard Test Methods for Determining Radiopacity for Medical Use
- EN 1618:1997 Catheters other than intravascular catheters - Test methods for common properties
- ISO EN ISO 20697:2018 Sterile drainage catheters and accessory devices for single use for kink testing

7. Comparison to predicate device and conclusion

Elements of Comparison	Subject Device	Primary Predicate Device	Remark
Device Name and Model	Ureteral Catheter (Type: Close Round Tip, Open Tapered Tip, Open Tip, Open Soft Tip, Open Cone Tip)	Open-End Ureteral Catheter, Open-End Ureteral Catheter Sof-Flex, EchoTip Open-End Ureteral Catheter, Open-End Flexi-Tip Ureteral Catheter, Flexi-Tip Ureteral Catheter (Closed End), Whistle Tip Ureteral Catheter, Round Tip Ureteral Catheter, Spiral Tip Ureteral Access Catheter, Pediatric Ureteral Catheter	--
510 (K) Number	K220036	K171662	--
Regulation number	21 CFR 876.5130	21 CFR 876.5130	SE
Regulation description	Urological Catheter and Accessories	Urological Catheter and Accessories	SE
Product code	KOD	KOD	SE
Class	II	II	SE
Indication for Use	The Ureteral Catheter is used for temporary urine drainage, delivery of irrigation fluids, injection of contrast agent to the urinary tract, navigation of a tortuous ureter, access, advancement or exchange of wire guides (open-ended catheters only).	Ureteral Catheters are indicated for access and catheterization of the urinary tract, including the following applications: • Delivery of contrast media • Drainage of fluids from the urinary tract • Delivery of irrigation fluids to the urinary tract • Navigation of a tortuous ureter • Access, advancement, or exchange of wire guides (open-ended catheters only) The Pediatric Ureteral Cathe-	SE Note 1

Elements of Comparison	Subject Device	Primary Predicate Device	Remark
		ter is indicated for access and catheterization of the urinary tract in pediatric patients, including the following applications: • Delivery of contrast media • Drainage of fluids from the urinary tract • Delivery of irrigation fluids to the urinary tract • Navigation of a tortuous ureter	
Prescription use	Yes	Yes	SE
Sterility	Sterile	Sterile	SE
Use	Single Use	Single Use	SE
Catheter OD (Fr size)	3Fr, 4Fr, 4.8Fr, 5Fr, 6Fr, 7Fr, 8Fr	3-9 Fr	SE Note 2
Catheter Length (cm)	70	10, 15, 70, 85, 120	SE Note 3
Catheter Materials	Radiopaque Polyvinyl chloride	Radiopaque Polyvinyl chloride or Polyurethane Radiopaque tubing or Polytetrafluoroethylene	SE Note 4
Components	The adapter and the guide wire	The following components may be included: Adapter, Stylet/Wire	SE Note 5
Tensile Strength	Identical to predicate device	Testing shows that there should be no fracture of catheter tips or shafts during proper clinical use.	SE Note 6
Leakage and Lumen Blockage	Identical to predicate device	Testing evaluated lumen blockage and leakage in a pressurized flow test. Lumen patency, dimensional length, inner diameter, and outer diameter were determined.	

Elements of Comparison	Subject Device	Primary Predicate Device	Remark
Kink Radius	Identical to predicate device	Testing determined the kink radius of the Ureteral Catheter tubing.	
Catheter-Hub Bond	Does not contain a Catheter Hub	Testing determined the tensile strength of the hub-to-shaft bond.	
Biocompatibility	Cytotoxicity test - ISO 10993-5: 2009, Sensitization - ISO 10993-10:2021, Skin irritation - ISO 10993-23:2021	Cytotoxicity – ISO MEM Elution Sensitization – Guinea Pig Maximization Irritation/ Intracutaneous Reactivity – Intracutaneous Study	SE

Comparison in Detail(s):

Note 1:

Although the specific language in the indication for use statement of the subject device is different from the predicate device, both have the same intended use applications and environment. Therefore, the subject device and predicate device have the same intended use.

Note 2:

Although the outer diameters of the subject device are different from predicate device, they are within the same range of the predicate device.

Note 3:

Although the length of the subject device is different from the predicate device, the predicate device contains a 70cm length, which is the subject device's catheter length.

Note 4:

Although there are differences in the materials, the subject device and predicate device meet the requirements of ISO 10993-5, ISO 10993-10 and ISO 10993-23. The subject device was also tested per ASTM F640-20.

Note 5:

The adaptor and guidewire components of the subject device are not identical to the adaptor and guidewire contained in the predicate device. However, bench testing was conducted to support equivalence.

Note 6:

Tensile strength, Flow rate, Resistance to liquid leakage under pressure, and biocompatibility testing demonstrate the subject device and predicate device have the same performance characteristics.

Final Conclusion:

The technological characteristics, features, specifications, materials, and indication for use of the Ureteral Catheter is substantially equivalent to the predicate device cited above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

8. Date of the summary prepared: December 16, 2022