May 22, 2023

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

Re: K220722
Trade/Device Name: Wellead® PVC Hydrophilic Urethral Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD
Dated: April 21, 2022
Received: April 24, 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
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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)*
K220722

Device Name
Wellead® PVC Hydrophilic Urethral Catheter

Indications for Use *(Describe)*
The Well Lead 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

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 8878-8628
- Contact Person (including title): Miss. Zhiqin Liang (RA Specialist); Ms. Jenny Zhu (RA Supervisor)
- E-mail: liangzhiqin@welllead.com.cn ; jenny_zhu@welllead.com.cn

2. Subject Device Information

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

3. Predicate Device and Reference Device Information

	Predicate Device	**Reference Device**
Sponsor	WELL LEAD MEDICAL CO. LTD	OASIS MEDIKAL URUNLER KIMYA SANAYI VE TIC A.S.
Device Name	Well Lead PVC Hydrophilic Urethral Catheter	Urinary Catheter for Intermittent Use
510(k) Number	K133615	K062444
Product Code	EZD	EZD
Regulation Number	876.5130	876.5130
Regulation Class	2	2

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

4. Device Description

The device is a urethral catheter used for intermittent catheterization. The device is a flexible single use urinary catheter inserted through the urethra to drain the bladder. The device is a disposable polyvinyl chloride (PVC) catheter coated with a hydrophilic coating (polyacrylamide) and an optional water sachet is included, which can activate the lubricant coating on the PVC. The device is generally for use in professional medical facilities and home environments.

The catheters come in sizes from 6Fr – 22Fr for the Male Model, 6Fr – 22Fr for the Female Model and 10Fr – 22Fr for the Tiemann Model. The catheter can connect to two different shapes of connector (called connector I and connector II) provided with the device. The connector enables the catheter to be connected to a urine bag or other collection apparatus. Urine can also be drained directly into the toilet.

The catheter is intended to be used for less than 24 hours based on the biocompatibility

information provided. It is expected that patients will use a new intermittent catheter multiple times a day (each time urine needs to be drained).

5. Indications for Use

The Well Lead 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.

6. Test Summary

PVC Hydrophilic Urethral Catheter has been evaluated for safety and performance by lab bench testing as follows:

- 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 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 irritation and skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation;
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity;

- ISO 10993-18: 2020, “Biological Evaluation of Medical Devices -Part 18: Chemical characterization of medical device materials within a risk management process”
- Surface finish
- Outer diameter
- Catheter length
- Strength
- Connector security
- Flow rate
- Kink stability
- Peak tensile force
- Coefficient of Friction

7. Substantial Equivalence Discussion

Elements of Comparison	Subject Device	Predicate Device	Reference Device	Remark
Device Name and Model	Well Lead PVC Hydrophilic Urethral Catheter	Well Lead PVC Hydrophilic Urethral Catheter	Urinary Catheter for Intermittent Use	--
510 (K) Number	K220722	K133615	K062444	--
Regulation number	21 CFR 876.5130	21 CFR 876.5130	21 CFR 876.5130	SE
Regulation description	Urological Catheter and Accessories	Urological Catheter and Accessories	Urological Catheter and Accessories	SE
Product code	EZD	EZD	EZD	SE
Class	II	II	II	SE
Indication for Use	The Well Lead PVC Hydrophilic Urethral Catheter is launched for clean intermittent	The Well Lead PVC Hydrophilic Urethral Catheter is launched for clean intermittent catheterization-CIC treatment and	Hi-Slip, Hi-Slip Plus and Hi-Slip Kit are all launched for Clean Intermittent Catheterization-CIC treatment and indicated for use by	SE

Elements of Comparison	Subject Device	Predicate Device	Reference Device	Remark
	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.	indicated for use by patients with chronic urine retention. The catheter is inserted into the bladder through the urethra for emptying the bladder.	patients with chronic urine retention. The catheter is inserted into the bladder through the urethra for emptying the bladder	
Prescription use	Yes	Yes	Yes	SE
Sterility	Sterile	Sterile	Sterile	SE
Sterilization Method	Water sachet is irradiation sterilized, and the final product is EO sterilized.	EO sterilized	EO sterilized	SE Note 1
Use	Single Use	Single Use	Single Use	SE
Type and Size	Standard Pediatric (6Fr, 8Fr, 10Fr) Adult (12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr)	Male (12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr)	Hi-Slip (urinary catheter) (Male 40 cm, CH08-24; Female 20 cm, CH08-18; Boys/Pediatric 30 cm, CH06-10; Girls/Pediatric 20 cm, CH06-10, Tiemann 40 cm, CH10-18)	SE Note 2
	Female Pediatric (6Fr, 8Fr, 10Fr) Adult (12 Fr, 14 Fr, 16Fr, 18Fr, 20 Fr, 22Fr)	Female (12Fr, 14Fr. 16Fr, 18Fr, 20Fr, 22Fr, 24Fr)	Hi-Slip Plus (urinary catheter and water sachet) (Male 40 cm, CH08-24; Female 20 cm,	

Elements of Comparison	Subject Device	Predicate Device	Reference Device	Remark
			CH08-18; Boys/Pediatric 30 cm, H06-10; Girls/Pediatric 20 cm, CH06-10)	
	Tiemann (10Fr, 12 Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr)	Pediatric (6Fr, 8Fr, 10Fr)	Hi-Slip Kit (urinary catheter, water sachet, Urine bag and Iodine swab) (Male 08-18CH; Female CH08-16CH; Pediatric Girls 06-10 CH; Pediatric Boys 06-10 CH; Tiemann l0-18 CH)	
		Tiemann (6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr)		
Catheter Materials	Polyvinylchloride catheter coated with polyacrylamide	Polyvinylchloride catheter coated with polyvinylpyrrolidone	Polyvinyl chloride catheter coated with polyvinylpyrrolidone	SE Note 3
Components	Water sachet	None	Water sachet Urine bag Iodine swab	SE Note 4

Comparison in Detail(s):

Note 1:

The terminal sterilization method of the subject device is EO Sterilization, just like the predicate device according to standard ISO 11135:2014 and has a sterility assurance level (SAL) of 10^-6. The water sachet is sterilized through radiation prior to final assembly.

Note 2:

The subject device adds - 6, 8, and 10 Fr- for the Male and Female catheter. The predicate device also has 6, 8, and 10 Fr. The reference device covers the 8-10 Fr Male and Female catheters, as well as the Tiemann tips. FDA has cleared 6Fr catheters in previous submissions, so it does not present different questions of safety and effectiveness. The sizes 6-10 Fr are indicated for pediatric patients, just like the predicate device.

Note 3:

The hydrophilic coating of subject device is polyacrylamide (PAM), while the predicate device is polyvinylpyrrolidone (PVP). Performance and biocompatibility testing was conducted to show that the device is substantially equivalent to the predicate device.

Note 4:

The subject device has an optional water sachet accessory. The water can lubricate the PVC catheter which has hydrophilic-coating, so it is easier for the catheter to pass through the urethra during urinary catheterization and into the bladder to drain urine. The water sachet of subject device are same as the Hi-Slip Plus Type (the reference device). The water sachet are sterilized via radiation. There are no different questions of safety or effectiveness raised.

Final Conclusion:

The technological characteristics and indication for use of the Wellead PVC Hydrophilic Urethral Catheter is substantially equivalent to the predicate device. The differences between the subject device and predicate devices do not raise different questions of safety or effectiveness.

8. Date of the summary prepared: May 16, 2023