June 6, 2024

Well Lead Medical (Hainan) Co., Ltd.
Irene Zhang
RA Specialist
No. 39, Mei'an 3rd Street,
Mei'an Ecological Science Park
Haikou, Hainan 571157
CHINA

Re: K233094
Trade/Device Name: Wellead® Latex Foley Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: May 8, 2024
Received: May 8, 2024

Dear Irene Zhang:

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.

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,

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)*
K233094

Device Name
Wellead® Latex Foley Catheter

Indications for Use *(Describe)*
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.

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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TRADITIONAL 510(K) SUMMARY

1. SUBMITTER INFORMATION

Applicant	Well Lead Medical (Hainan) Co., Ltd, No. 39, Mei'an 3rd Street, Mei'an Ecological Science Park, 571157, Haikou, Hainan, China,
Official Correspondent	Ms. Jenny Zhu (RA Supervisor), E-mail: jenny_zhu@welllead.com.cn Miss. Irene Zhang (RA Specialist), E-mail: zhangshanshan@welllead.com.cn
Date Prepared	June 04, 2024

2. DEVICE NAME

Trade Name of the Device	Wellead® Latex Foley Catheter
Common Name:	Foley Catheter
Classification Name:	Urological Catheter and Accessories
Classification Regulation:	21 CFR 876.5130
Device Class:	II
Product Code:	EZL
Panel:	Gastroenterology/Urology

3. PREDICATE AND REFERENCE DEVICES IDENTIFICATION

Predicate: Well Lead Latex Foley Catheters (K082815)
Reference: Medline Latex Foley Catheter (K071423)

Predicate device was not subjected to any design related recall.

4. DEVICE DESCRIPTION:

The Latex Foley Catheter is inserted through the urethra during urinary catheterization and goes into the bladder for urine drainage or irrigation. It consists of a shaft, a drainage funnel, an inflation funnel, an irrigation funnel (if present), a balloon and a valve. The device is made from latex with silicone coating and available in different types (e.g., straight, Tiemann, female etc.) and sizes for adult and pediatric use.

5. INDICATIONS FOR USE:

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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

	K233094 (Subject Catheter)	K082815 (Predicate Device)	K071423(Reference)
Device Name	Well Lead Latex Foley Catheter	Well Lead Latex Foley Catheters	Medline Latex Foley Catheter
Indication For use	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.	Two-Way Catheter – urethral catheterization for bladder drainage for urological use only. Three-Way Catheter - urethral catheterization for bladder drainage and bladder irrigation for Urological use only.	The Medline Latex Foley Catheter is intended to be used as a urological catheter inserted through the urethra for the purpose of draining urine and other fluids from the urinary tract.
Device Type	2-Way and 3-way Foley Catheter	2-Way and 3-way Foley Catheter	2-Way and 3-way Foley Catheter
Catheter tube Material	Latex	Latex	Latex
Catheter French Size (Fr.)	6-30Fr.	6-30Fr.	6-30Fr.
Catheter Shaft Effective Length (mm)	180±25 to 300±25	180±25 to 300±25	240 to 380
Balloon Volume	3mL, 3-5mL, 5ml, 5-10ml,10ml,5-15ml, 15ml, 15-30mL, 20ml, 30ml	3ml, 5ml, 30ml	3ml, 5ml, 30ml
Stylet	Present	None	Present
Catheter Tip	Straight and Coude	Straight	Straight and Coude
Duration of Use	less than 30 days	up to 30 days	Not provided
Use environment	Health care facilities	Health care facilities	Health care facilities
Surface Coating	Silicon Coating	Silicon Coating	Silicon Elastomer
Sterile and Single Use	Yes	Yes	Yes

As evidenced by the above table, both the subject and the predicate devices have same intended use but differ in technological characteristics. Performance testing was conducted on the subject device, and it was established that the differences in technological characteristics do not raise different questions of safety or effectiveness.

7. SUMMARY OF NONCLINICAL TESTING:

The reference device was used to justify the Coude tip and the use of a stylet with the pediatric models of the subject catheter.

Below is a list of the tests that were performed and successfully completed for the subject device per the specified guidance and standards:

- Biocompatibility testing according to ISO 10993-1:2018 - *Biological evaluation of medical devices*

  — Part 1: Evaluation and testing within a risk management process and FDA Guidance "*Use of International Standard ISO 10993-1*" (2016).

- The EO sterilization process was validated in accordance with ANSI/AAMI/ISO 11135:2014.

- The following bench performance testing were conducted per ASTM F623-19 and the FDA guidance document, '*Conventional Foley Catheters - Performance Criteria for Safety and Performance Based Pathway'*-
  - Flow Rate through Drainage Lumen
  - Balloon Integrity (Resistance to Rupture)
  - Inflated Balloon Response to Traction
  - Balloon Volume Maintenance
  - Balloon Size and Shaft Size
  - Deflation Reliability (Failure to Deflate)

- For 6-10Fr. and 28-30 Fr. catheters, the bench performance testing was conducted per BS EN 1616:1997 as theses French sizes are outside of the scope of ASTM F623-19.

All pre-determined acceptance criteria were met.

8. CONCLUSIONS

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate device.