April 8, 2021

Well Lead Medical CO., LTD.
Jenny Zhu
RA Specialist
C-4# Jinhu Industrial Estate, Hualong, Panyu
Guangzhou, Guangdong 511434
China

Re: K202134
Trade/Device Name: All Silicone Foley Catheter with Temperature Sensor
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: March 5, 2021
Received: March 11, 2021

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,

Sharon M. Andrews -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)*
K202134

Device Name
All Silicone Foley Catheter with Temperature Sensor

Indications for Use *(Describe)*
All Silicone Foley Catheter With Temperature Sensor is intended for use in the drainage/collection of urine from the urinary bladder and simultaneous monitoring of the body core temperature during surgical or post-surgical intervals.

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.

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510(k) Summary – K202134

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

1. Submitter Information

Date Prepared:	April 6, 2021
Submitter:	WELL LEAD MEDICAL CO., LTD. Address: C-4 # Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China
Contact Person:	Jenny Zhu RA Specialist WELL LEAD MEDICAL CO., LTD. Email: jenny_zhu@welllead.com.cn Tel: +86-20-84758878
Device Name:	All Silicone Foley Catheter with Temperature Sensor
Common Name:	Foley Catheter
Regulation Number:	21 CFR 876.5130
Regulation Name:	Urological catheter and accessories

Product Code:	EZL (catheter, retention type, balloon)
Regulatory Class:	Class II
Predicate Device(s):	K091516-Well Lead All Silicone Foley Catheter with Temperature Sensor

2. Intended Use

All Silicone Foley Catheter with Temperature Sensor is intended for use in the drainage/collection of urine from the urinary bladder and simultaneous monitoring of the body core temperature during surgical or post-surgical intervals.

3. Device Description

The All Silicone Foley Catheter with Temperature Sensor is made from medical grade silicone, consists of temperature sensor for monitoring core body temperature and Foley catheter including a shaft, drainage funnel, inflation funnel, balloon, valve, and X-ray opaque line. The device is provided sterile by ethylene oxide and is for single use only. It is provided in a variety of sizes and color-coded by size.

4. Substantial Equivalence—Comparison to Predicate Device

The All Silicone Foley Catheter with Temperature Sensor has the same intended use as the predicate device. It is intended for use in the drainage/collection of urine from the urinary bladder and simultaneous monitoring of the body core temperature during surgical or post-surgical intervals.
The subject device uses the same design, materials, and manufacturing technique as the predicate device; and therefore, the subject and predicate device have the same technological characteristics.

The All Silicone Foley Catheter with Temperature Sensor differs from the predicate device in MR compatibility. The predicate device is labeled “Safety in MRI Not Evaluated” and the subject device is labeled “MR Conditional.”

5. Summary of Non-Clinical Testing

Bench-top testing was conducted to assure conformance to the following standards:

- ASTM F2052-15, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2119-07 (Reapproved 2013), Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- ASTM F2182-19, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
- ASTM F2213-17, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- ASTM F2503-13, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

The performance data support that the subject device can be labeled “MR Conditional.”

6. Conclusion

The All Silicone Foley Catheter with Temperature Sensor is substantially equivalent to predicate device.