



Food and Drug Administration  
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December 15, 2014

Well Lead Medical Co LTD  
Han Guang Yuan  
General Manager  
C-4<sup>#</sup> Jinhu Industrial Estate, Hualon, Panyu  
Guangzhou, 511434  
P.R. China

Re: K140667  
Trade/Device Name: Well Lead Hydrophilic Silicone Foley Catheter  
Regulation Number: 21 CFR 876.5130  
Regulation Name: Urological Catheter and Accessories  
Regulatory Class: Class II  
Product Code: EZL

Dear Han Guang Yuan,

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Benjamin R. Fisher -A**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K140667

Device Name: Well Lead Hydrophilic Silicone Foley Catheter

Indications for Use:

The Well Lead Hydrophilic Silicone Foley Catheter is intended for use for bladder management including urine drainage, collection and measurement. The Catheter is passed through the urethra during urinary catheterization and into the bladder to drain urine. The Three-way Catheter provides a lumen that is used for bladder irrigation.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

## 510(k) Summary

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

Date: 2014/03/14

Submitter: WELL LEAD MEDICAL CO., LTD.  
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Guangzhou, 511434, P.R. China

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Device Name: Well Lead Hydrophilic Silicone Foley Catheter  
Regulation Number: 876.5130  
Classification Name: Urological catheter and accessories  
Product Code: EZL  
Regulatory Class: Class II

Device Description: The Well Lead Hydrophilic Silicone Foley Catheter is sterile, single patient use, urinary drainage catheter that is made from silicone and with a hydrophilic coating. The Catheter is available in two types, Two-way and Three-way Silicone Foley Catheter, it is supplied in French size ranging from 6 to 26 and balloon size 1.5cc to 30cc. The 6Fr, 8Fr and 10Fr catheters are for pediatric, and others are for adult.

Intended Use: The Well Lead Hydrophilic Silicone Foley Catheter is intended for use for bladder management including urine drainage, collection and measurement. The Catheter is passed through the urethra during urinary catheterization and into the bladder to drain urine. The Three-way Catheter provides a lumen that is used for bladder irrigation.

Predicate Device(s): K984084- Bardex® Lubri-Sil™ Foley Catheter  
K002868-Bardex® Lubri-Sil™ 3-way Foley Catheter  
K070508-Bardex® Lubri-Sil® All-Silicone Lubricious Coated Foley Catheter 6Fr

Substantial Equivalence: The Well Lead Hydrophilic Silicone Foley Catheters described in this 510(k) have similar technological and performance characteristics to the predicate devices. The proposed device are manufactured from silicone and have a hydrophilic outer coating. The predicate devices are manufactured from similar materials such as silicone and have a lubricious hydrophilic coating. The similarities and differences between the proposed and predicate devices have been identified and explained in the comparison matrix which has been included in Section 12 of this submission. These differences have no effect on safety and effectiveness, or raise different questions of safety and effectiveness.

Test Data: The Well Lead Hydrophilic Silicone Foley Catheters meet the following performance requirements per testing conducted according to ASTM F623-99, when appropriate, and/or Well Lead testing/ acceptance criteria:

NOTE: ASTM F623-99 is applicable only to 2-way catheters, however, the test methods described therein will be utilized to test 3-way catheters.

- Flow Rate Through Drainage Lumen
- Balloon Integrity (Resistance to Rupture)
- Inflated Balloon Response to Pullout
- Balloon Volume Maintenance
- Balloon Size and Shaft Size
- Deflation Reliability (Failure to Deflate)
- Coefficients of Friction

Testing on aged product indicates that application of the coating has no adverse effect on the base material of the shaft or balloon.

The Well Lead Hydrophilic Silicone Foley Catheter passed biocompatibility testing per ISO 10993-1 (Cytotoxicity, Implantation, Irritation, Sensitization, Systemic Toxicity)

Testing data and results are included in this submission.