DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 28, 2014

Well Lead Medical Co., Ltd.
Han Guang Yuan
General Manager
C-4# Jinhu Industrial Estate
Hualong, Panyu
Guangzhou, 511434
P.R. China

Re: K142563
Trade/Device Name: Well Lead PVC Urethral Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: EZD
Dated: September 10, 2014
Received: September 11, 2014

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,

Herbert P. Lerner -S

for

Benjamin Fisher
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): K142563

Device Name: Well Lead PVC Urethral Catheter

Indications for Use:
The Well Lead PVC Urethral Catheter is launched for clean intermittent catheterization(CIC) treatment. It is intended for use in the drainage of fluid from the urinary tract.

Prescription Use X	OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(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:	2014/09/10
Submitter:	WELL LEAD MEDICAL CO., LTD. Address:C-4 # Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China
Contact Person:	Han Guang Yuan General Manager WELL LEAD MEDICAL CO., LTD. Email: huangkg@welllead.com.cn Tel: +86-20-84758878 Fax:+86-20-84758224
Device Name:	Well Lead PVC Urethral Catheter
Regulation Number:	876.5130
Classification Name:	Urological catheter and accessories
Product Code:	EZD
Regulatory Class:	Class II
Device Description:	The Well Lead PVC Urethral Catheter is sterile, single patient use, urinary drainage catheter that is made from PVC. The Catheter is inserted through the urethra and used to pass fluids from the urinary tract. The Catheter is supplied in French size ranging from 6 to 24. The Catheters come in sizes from 12Fr-24Fr for Male, 12Fr-24Fr for Female and 6Fr-10Fr for Pediatric 2-12 years old.
Intended Use:	The Well Lead PVC Urethral Catheter is launched for clean intermittent catheterization(CIC) treatment. It is intended for use in the drainage of fluid from the urinary tract.
Predicate Device(s):	K100302- Medline PVC Urethral Catheter K133615- Well Lead PVC Hydrophilic Urethral Catheter
Substantial Equivalence:	The Well Lead PVC Urethral Catheters described in this 510(k) have similar technological and performance characteristics to the predicate devices. The proposed device is manufactured from PVC. The predicate devices are manufactured from similar materials such as PVC. 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 PVC Urethral Catheters meet the following performance requirements per testing conducted according to ASTM F623-99 & EN1616:1997, when appropriate, and/or Well Lead testing/ acceptance criteria:
NOTE: ASTM F623-99 is applicable only to 2-way foley catheter, however, the test methods described therein will be utilized to test 1-way urethral catheter.

- Dimensions
- Flow Rate
- Strength of the Catheter
- Connector Security

The Well Lead PVC Urethral Catheter passed biocompatibility testing per ISO 10993-1 (Cytotoxicity, Irritation, Sensitization)
Testing datas and results are included in this submission.