510(k) SUMMARY
(as required by 807.92)

FEB 2 4 2014

Regulatory Correspondent:
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Submitter of 510(k):
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Date of Summary: 10/18/2013

Trade/Proprietary Name: Well Lead PVC Hydrophilic Urethral Catheter

Common/Usual Name: Catheter, Straight

Classification Name: Class II

Product Code: EZD

Intended 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.

Device Description:
The Well Lead PVC Hydrophilic Urethral Catheter is a flexible tubular single use urinary catheter that is inserted through the urethra to allow drainage of the bladder. The device consists of disposable polyvinyl chloride catheter (medical grade PVC) coated with hydrophilic polymer. When the catheter is immersed in water for 30 seconds it becomes slippery and ready to use.

The catheters come in sizes from 12Fr-24Fr for Male, 12Fr-24Fr for Female and 6Fr-10Fr for Pediatric.
Sizes 6Fr – 10Fr are for Children ages 2 years old to less than 12 years old, Sizes 12Fr - 24Fr are for 12 years old and over.

Predicate Device: K062444 – Hi-Slip Single Use Hydrophilic Urinary Catheter.

Substantial Equivalence:
The Well Lead PVC Hydrophilic Urethral Catheters are substantially equivalent in intended use and technological characteristics to the HI-Slop Single Use Hydrophilic Urethral Catheters. Any difference that exists between the Well Lead PVC Hydrophilic Urethral Catheters and the predicate device do not affect safety or effectiveness, or raise different questions of safety and effectiveness.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS		
Comparison Elements	**Applicant Device**	**Predicate Device**
510k Number		K062444
Device Name	Well Lead PVC Hydrophilic Urethral Catheters	Hi-Slip Single Use Hydrophilic Urinary Catheter
Technical Data		
Device Composition	Polyvinyl Chloride catheter coated with polyvinyl pyrrolidone	Polyvinyl Chloride catheter coated with polyvinyl pyrrolidone
Sizes	Male (12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr)	Male 40cm, CH08-24
	Female (12Fr, 14Fr. 16Fr, 18Fr. 20Fr, 22Fr, 24Fr)	Female 20cm, CH08-18
	Pediatric (6Fr, 8Fr, 10Fr)	Boys/Pediatric 30cm, CH06-10
	Tiemann (6Fr-24Fr)	Girls/Pediatric 20cm, CH06-10
		Tiemann 40cm, CH10-18
Design Features	Single lumen shaft, multi-port adaptor, 1 cuff	Double lumen shaft, multi-port adaptor, 1 cuff
Function of the Device	Intermittent Catheterization	Intermittent Catheterization
Features of the device	Hydrophilic Coated, slippery surface. Low friction between catheter and urethral mucosa	Hydrophilic Coated, slippery surface. Low friction between catheter and urethral mucosa
Sterility	EO	EO
Packaging	Peel Pack	Peel Pack

Sterilization and Shelf-Life

Sterilization was completed using the ethylene oxide process. The validation was completed according to ISO 11135-1. The sterility assurance level is SAL 10^{-6}. Ethylene oxide residual is validated according to EN ISO 10993 part 7 for Limited Exposure Devices of 4mg/day for ETO and 9mg/day for ECH.

The packaging material complies with requirements of ISO 11607-1, sealing validation per ISO 11607-2 and GHTF-SG3-N99-10:2004. Accelerated aging was completed to validate a shelf life of 5 years.

Packaging Testing		
Test Performed	**Standard Tested to**	**Result**
Tensile Seal Strength Test	ISO 11607	Complies
Impermeability and Continuity of Seals formed by fusion test	ISO 11607	Complies
Vacuum Leak Test	ISO 11607	Complies
Agar contact-attack test	ISO 11607	Complies

Performance /Non-Clinical Testing:

Non-Clinical Testing		
Test Performed	**Standard Tested to**	**Result**
Analysis of Flow Rate	EN1616:1997/A1:1999	Complies
Analysis of Strength of the Catheter	EN1616:1997/A1:1999	Complies
Analysis of Connector Security	EN1616:1997/A1:1999	Complies
Analysis of Coefficients of Friction	EN1616:1997/A1:1999	Complies

Testing was completed on 3 different size catheters, 8Fr (pediatric size), 14Fr and 24Fr, based on the data generated from the testing on it can be concluded that the Well Lead PVC Hydrophilic Urethral Catheters are substantially equivalent to the Hi-Slip Single Use Hydrophilic Urinary Catheters.

Biocompatibility Testing:

Based on ISO 10993-1:2009 Annex A Table A.1 – Well Lead PVC Hydrophilic Urethral Catheters Category is considered a Surface Device that comes in contact with the Mucosal Membrane at for limited exposure. The following tests were performed:

In Vitro Cytotoxicity – ISO 10993-5:2009 and ISO 10993-12:2012
Delayed Contact Sensitization Study – ISO 10993-10:2010 and ISO 10993-12:2012
Penile Irritation Test – ISO 10993-10:2010 and ISO 10993-12:2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 24, 2014

Well Lead Medical CO., LTD.
% John O'Brien
Consultant Level I
AJW Technology Consultants, Inc.
445 Apollo Beach Blvd.
Apollo Beach, FL 33572

Re: K133615
Trade/Device Name: Well Lead PVC Hydrophilic Urethral Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: January 27, 2014
Received: January 31, 2014

Dear John O'Brien,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133615

Device Name: Well Lead PVC Hydrophilic Urethral Catheter

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.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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