510(k) SUMMARY - K091516
(as required by 807.92(c))

OCT 16 2009

Regulatory Correspondent:

Regulatory and Marketing Services, Inc
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Submitter of 510(k):

Well Lead Medical Device Instruments Ltd.
A4-1# Jinhu Industrial Estate
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Date of Summary: 5/18/09

Trade/Proprietary Name: Well Lead all Silicone Foley Catheter with Temperature Sensor

Classification Name: Urological Catheter and Accessories

Product Code: EZL

Intended Use: The Well Lead all Silicone Foley Catheters with Temperature Sensor are 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.

Device Description: The Well Lead all Silicone Foley Catheters with Temperature are two-way Foley Catheters which are used in the drainage/collection of urine from the urinary bladder and simultaneous monitoring of the body core temperature during surgical or post-surgical intervals.

Predicate Device:	K873448 – Smiths Foley Catheter Temperature Sensor K082815 – Well Lead Silicone and Latex Foley Catheters
Substantial Equivalence:	Well Lead Medical Instruments claims the proposed devices to be substantially equivalent to the devices previously cleared by FDA in K873448 and K082815. Well Lead Medical Products claims this equivalence because the proposed devices have an equivalent intended use, manufacturing materials, operating principals and physical operational specifications as compared to the predicate devices. The similarities and differences between the proposed and predicate device has been identified and explained on the comparison chart which has been included in section 9 of this submission.
Performance Testing:	All of the appropriate testing for the Foley Catheters was completed and submitted in the previously cleared submission K082815 all the materials are the same as the Foley Catheters in this submission. The testing for the Temperature Sensor can be found in Section 11 the Performance Testing section and in Section 14 Biocompatibility Testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Well Lead Medical Co., Ltd.
% Mr. Arthur Ward
President
Regulatory and Marketing Services, Inc.
962 Allegro Lane
APOLLO BEACH FL 33572

OCT 16 2009

Re: K091516
Trade/Device Name: Well Lead All Silicone Foley Catheters with Temperature Sensor
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: September 1, 2009
Received: September 11, 2009

Dear Mr. Ward:

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.

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K091516

Indications for Use

510(k) Number (if known): K091516

Device Name: Well Lead All Silicone Foley Catheters With Temperature Sensor

Indication for use:

The Well Lead All Silicone Foley Catheters With Temperature Sensor are 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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE –CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091516

Traditional 510(k) for Well Lead All Silicone Foley Catheter With Temperature Sensor