OCT 0 8 2008

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k): **Well Lead Medical Instruments**
A4-1# Jinhu Industrial Estate
Hualong, Pan Yu
Guangdong, China 511434

Phone: 8620 84752978
Fax: 8620 84758224

Contact Person: Han Guang Yuan

Date of Summary: 5/09/07

Trade/Proprietary Name: Well Lead All Silicone Foley Catheters
Well Lead Latex Foley Catheters

Classification Name: **Silicone** – Catheter, Retention Type, Balloon
Latex - Urological catheter and accessories

Product Code: **Silicone** – EZL
Latex - MJC

Intended Use:

Two-Way Catheter – Urethral catheterization for bladder drainage for Urological use only

Three Way Catheters – Urethral catheterization for bladder drainage and bladder irrigation for urological use only

Device Description:

The Well Lead Latex and Silicone Foley catheters are two-way Foley catheters which are placed in the bladder throught the urethra. The urine drains out through the catheter into a collection device attached to the catheter.

Device Performance:

The dimensions, design, sterility and packaging of the Well Lead Foley Catheters (silicone and latex) conform to ASTM F 623-99.

Predicate Device:

Silicone – K981612 – Rochester Medical all Silicone Foley Catheter
Latex – K040658 – Bard I.C

Substantial Equivalence:

Well Lead Medical Instruments claims the proposed devices to be substantially equivalent to the devices previously cleared by FDA in K981612 and K040658. Well Lead Medical Products claims this equivalence because the proposed devices have an equivalent intended use, manufacturing materials, operating principles, and physical, operational specifications as compared to the predicate devices.

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 9 of this submission. Additionally, this matrix is included as an attachment to the 510(k) Summary. These differences have no effect on safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

Well Lead Medical Instruments Co.
% Mr. Jay Y. Kogoma
Intertek Testing Services NA, Inc.
2307 E. Aurora Road, Unit B7
TWINSBURG OH 44087

Re: K082815
Trade/Device Name: Well Lead Silicone and Latex Foley Catheters
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: September 24, 2008
Received: September 25, 2008

Dear Mr. Kogoma:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082815

Device Name: Well Lead Silicone and Latex Foley Catheters

Indications for Use:

Two – Way Catheters – Urethral catheterization for bladder drainage for urological use only.

Three – Way Catheters – Urethral catheterization for bladder drainage and bladder irrigation for urological use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 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 K082815