



Food and Drug Administration
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January 7, 2016

Well Lead Medical Co. Ltd
Huang Gen
Regulatory Affairs Manager
C-4 Jinhua Industrial Estate
Hualong, Panyu
Guangzhou, 511434 CN

Re: K151084
Trade/Device Name: Well Lead Ureteral Access Sheath
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FED
Dated: November 24, 2015
Received: November 27, 2015

Dear Huang Gen,

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,



Jeffrey W. Cooper -S
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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)

K151084

Device Name

Well Lead Ureteral Access Sheath

Indications for Use (Describe)

The Well Lead Ureteral Access Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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

Date: 2015/04/20

Submitter: WELL LEAD MEDICAL CO., LTD.
Address: C-4 # Jinhua Industrial Estate, Hualong, Panyu,
Guangzhou, 511434, P.R. China

Contact Person: Huang Kai gen
Regulatory Affairs Manager
WELL LEAD MEDICAL CO., LTD.
Email: huangkg@welllead.com.cn
Tel: +86-20-84758878
Fax: +86-20-84758224

Device Name: Well Lead Ureteral Access Sheath
Regulation Number: 876.1500
Classification Name: Endoscope and accessories
Product Code: FED
Regulatory Class: Class II

Device Description: The Well Lead Ureteral Access Sheath is a single use sterile device, provides ureteral dilation and a continuous working channel for the introduction of endoscopes and instruments during ureteral access procedures. The Ureteral Access Sheath is comprised of three components: sheath, dilator and connector. The outer surface of the sheath has a hydrophilic coating. When activated, the hydrophilic feature allows for easier insertion and removal of the sheath. The sheath is offered in three French sizes: 10Fr, 12Fr and 14Fr, and range in length from 13cm (shortest) to 55cm (longest).

Intended Use: The Well Lead Ureteral Access Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract.

Predicate Device(s): K123675-Re-Trace Ureteral Access Sheath
K140323-Navigator™ HID Ureteral Access Sheath Set

Substantial Equivalence: The Well Lead Ureteral Access Sheath described in this 510(k) have similar technological and performance characteristics to the predicate devices. The proposed device is substantially equivalent in performance, indication for use, design and materials to 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 12 of this submission. These differences have no effect on safety and effectiveness, or raise different questions of safety and effectiveness.

Test Data: The following performance testing was conducted:

- Attachment security
- Bending resistance
- Coefficients of Friction
- Determining the Dimensions

Testing on aged product indicates that application of the coating has no adverse effect on the base material of the Ureteral Access Sheath.

The Well Lead Ureteral Access Sheath passed biocompatibility testing per ISO 10993-1 (Cytotoxicity, Irritation, Sensitization)

Testing data and results are included in this submission.