December 9, 2020

Well Lead Medical Co., LTD.
Jenny Zhu
RA Specialist
C-4# Jinhu Industrial Estate, Hualong, Panyu
Guangzhou, Guangdong 511434
China

Re: K203119
Trade/Device Name: ClearPetra Suction-Evacuation Sheath
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FED, FAJ, FGA
Dated: October 14, 2020
Received: October 16, 2020

Dear Jenny Zhu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark J. Antonino, M.S.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203119

Device Name
ClearPetra Suction-Evacuation Sheath

Indications for Use *(Describe)*
The ClearPetra Suction-Evacuation Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. It is designed to establish a conduit for the treatment of urinary stones or other urinary diseases during endoscopic procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information

Date:	11/18/2020
Submitter:	WELL LEAD MEDICAL CO., LTD. Address: C-4 # Jinhu Industrial Estate, Hualong, Panyu, Guangzhou, 511434, P.R. China
Contact Person:	Jenny Zhu RA Specialist WELL LEAD MEDICAL CO., LTD. Email: jenny_zhu@welllead.com.cn Tel: +86-20-84758878-8029
Device Name:	ClearPetra Suction-Evacuation Sheath
Regulation Number:	21 CFR 876.1500
Regulation Name:	Endoscope and Accessories
Product Code:	FED–Endoscopic Access Overtube, Gastroenterology-Urology FAJ–Cystoscope And Accessories, Flexible/Rigid FGA–Kit, Nephroscope
Regulatory Class:	Class II
Predicate Device(s):	K161110- ClearPetra Suction-Evacuation Sheath

2. Indications for use

The ClearPetra Suction-Evacuation Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. It is designed to establish a conduit for the treatment of urinary stones or other urinary diseases during endoscopic procedures.

3. Device Description

The ClearPetra Suction-Evacuation Sheath consists of a straight distal tube and a proximal bifurcated tube. The distal straight tube of the ureteral access sheath is reinforced with metal wires for torque resistance. One segment of the proximal bifurcated tube is straight and is contiguous with the distal tube. The other is constructed in an oblique angle with a longitudinal pressure control vent. An obturator is included for the insertion of the sheath. The obturator can be locked to the proximal end of the straight tube using a luer lock mechanism. A rubber cap with central aperture is included as an accessory. It is to be placed at the proximal end of the straight tube after the removal of the obturator. The oblique tube is to be connected directly to a negative pressure aspirator with a clear tube or alternatively, connected to a specimen collector (packed separately) then onto a negative pressure aspirator.

Modification:

The ClearPetra Suction-Evacuation Sheath differs from the predicate device as below:
(1) Product Size Change: Add 24Fr, 26Fr in product model of ClearPetra Nephrostomy Sheath;
(2) Product Length Change: Add 15cm in product model of ClearPetra Nephrostomy Sheath.
The intended use of the modified device, as described in its labeling, has not changed as a result of the modification.

4. Substantial Equivalence—Comparison to Predicate Device

The predicate device to which we claim equivalence is the ClearPetra Suction-Evacuation Sheath (K161110).
The ClearPetra Suction-Evacuation Sheath maintains the same intended use as the predicate device. It is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. It is designed to establish a conduit for the treatment of urinary stones or other urinary diseases during the endoscopic procedures. The proposed device and the predicate device consist of the same fundamental technology.

The ClearPetra Suction-Evacuation Sheath differs from the predicate device in product model of ClearPetra Nephrostomy Sheath as below:
(1) Product Size Change: Add 24Fr, 26Fr in product model of ClearPetra Nephrostomy Sheath;
(2) Product Length Change: Add 15cm in product model of ClearPetra Nephrostomy Sheath.
The modification has not altered the fundamental scientific technology of the predicate ClearPetra Suction-Evacuation Sheath. It has well-established methods are available to evaluate the change as well as all performance data necessary to support SE can be reviewed in a summary or risk analysis format.

Therefore, the modified ClearPetra Suction-Evacuation Sheath is substantially equivalent to the current legally marketed ClearPetra Suction-Evacuation Sheath (K161110) device. The differences between the ClearPetra Suction-Evacuation Sheath and the predicate device raise no different issues of safety and effectiveness.

A Risk Analysis was conducted and is detailed in the Design Control Summary Section. No new issues of safety and effectiveness were identified during this process.

The ClearPetra Suction-Evacuation Sheath and the predicate device consist of the same fundamental technology and are sterilized with acceptable methods. Below is a comparison table that summarizes the technological characteristics of the proposed and predicate device.

Table 5-1 – Comparison Between Subject Device & Predicate Device

Comparison between proposed device and predicate device			
Comparison Items	**Subject Device**	**Predicate Device**	**Verdict**
Product Name	ClearPetra Suction-Evacuation Sheath	ClearPetra Suction-Evacuation Sheath	Same
Model Name	ClearPetra Nephrostomy Sheath	ClearPetra Nephrostomy Sheath	Same
510k Number	Applying	K161110	Same
Product Code	FED, FAJ, FGA	FED, FAJ, FGA	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Regulatory Class	Class II	Class II	Same
Review Panel	Gastroenterology/Urology	Gastroenterology/Urology	Same
Indications for Use	It is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. It is designed to establish a conduit for the treatment of urinary stones or other urinary diseases during the endoscopic procedures.	It is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. It is designed to establish a conduit for the treatment of urinary stones or other urinary diseases during the endoscopic procedures.	Same
Patient Population	Patients undergoing endoscopic procedures, through percutaneous passages	Patients undergoing endoscopic procedures, through percutaneous passages	Same

Comparison between proposed device and predicate device			
Comparison Items	**Subject Device**	**Predicate Device**	**Verdict**
Material	PE, PA	PE, PA	Same
Sterilization Method	EO sterilized	EO sterilized	Same
Size	10Fr to 26Fr	10Fr to 22Fr	Different. Since the new product specification is not far outside cleared product specification, the change could not significantly affect the device's safety or effectiveness. The new product specifications were tested as per Product Specification.
OD of Obturator	Compatible with 10Fr-26Fr sheath	Compatible with 10Fr-22Fr sheath	Same
Length	13cm to 55cm	13cm to 55cm	Similar Although a modified dimension is within a range of dimensions previously cleared for the original device, the change could not significantly affect the device's safety or effectiveness. The new product specifications were tested as per Product Specification.
Component	Sheath, Obturator, Connector, Rubber Cap	Sheath, Obturator, Connector, Rubber Cap	Similar
Design Drawing			Same
Sterilization Method	EO sterilized	EO sterilized	Same
Single Use	Yes	Yes	Same

Comparison between proposed device and predicate device			
Comparison Items	**Subject Device**	**Predicate Device**	**Verdict**
Biocompatibility	ISO 10993-1 Cytotoxicity, Irritation, Sensitization, Acute System Toxicity, Material mediated pyrogencity	ISO 10993-1 Cytotoxicity, Irritation, Sensitization, Acute System Toxicity	Similar The subject device's materials in contact were tested as per ISO 10993-11 for Material mediated pyrogencity.

Discussion

Although there is a bit difference of the product specification and dimension between the predicate device and subject device, they have the same technological features, performance, intended use and manufactured in the same manner as currently marketed device. The newly change in subject device has been evaluated by a well-established method of bench testing. And the data has been reviewed in a summary or risk analysis format to show that modification does not affect the safety and effectiveness.

5. Summary of Non-Clinical Testing

The following performance testing comparing the modified device to the predicate device was conducted.

- Performance Bench testing has been conducted to verify that the performance of the proposed ClearPetra Suction-Evacuation Sheath is substantially equivalent to the predicate device, and that the ClearPetra Suction-Evacuation Sheath will perform as intended. Bench-top testing was conducted to assure conformance to the following standards:
  - Product Specification
- The following Biocompatibility testing was performed in accordance with ISO 10993-1.
  - Cytotoxicity
  - Sensitization
  - Irritation/ Intracutaneous reactivity

- Acute System Toxicity
- Material Mediated Pyrogencity

- Sterilization by ethylene oxide has been validated for ClearPetra Nephrostomy Sheath.

Conclusions Drawn from the Non-Clinical Testing

The performance and biocompatibility testing provided in this submission demonstrate that the modified ClearPetra Suction-Evacuation Sheath is as safe and effective and performs as well as the predicate device and therefore supports the determination of substantial equivalence.

6. Conclusion

The ClearPetra Nephrostomy Sheath is substantially equivalent to predicate device. Based on the intended use, principle of operation, performance characteristics, and technological characteristics, the proposed ClearPetra Nephrostomy Sheath is substantially equivalent to and as safe, as effective and performs as the legally marketed predicate device.

7. Summary Prepared Date

18 November 2020