



Food and Drug Administration  
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October 12, 2016

WELL LEAD MEDICAL CO., LTD.  
Han Guang Yuan  
General Manager  
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Guangzhou, Guangdong 511434  
China

Re: K161110  
Trade/Device Name: ClearPetra Suction-Evacuation Sheath  
Regulation Number: 21 CFR§ 876.1500  
Regulation Name: Endoscope and Accessories  
Regulatory Class: II  
Product Codes: FED, FAJ, FGA  
Dated: September 10, 2016  
Received: September 14, 2016

Dear Han Guang Yuan:

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,

**Benjamin R. Fisher -S**

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

510(k) Number (if known): K161110

Device Name: ClearPetra Suction-Evacuation Sheath

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 the endoscopic procedures.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

OR

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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_ Concurrence of CDRH, Office of Device Evaluation (ODE) \_\_\_\_\_

## 510(k) Summary

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

Date: 2016/09/10

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Device Name: ClearPetra Suction-Evacuation Sheath  
Trade Name: ClearPetra Suction-Evacuation Sheath  
Common Name: Ureteral Access Sheath, Cystoscope Sheath, Nephrostomy Sheath, Endoscopic Access Overtube

Regulation Number: 876.1500 Endoscope and accessories

Classification Name: FED—Endoscopic Access Overtube, Gastroenterology-Urology  
21 CFR 876.1500; Class II

FAJ—Cystoscope And Accessories, Flexible/Rigid  
21 CFR 876.1500; Class II

FGA—Kit, Nephroscope  
21 CFR 876.1500; Class II

Product Code: FED—Endoscopic Access Overtube, Gastroenterology-Urology  
FAJ—Cystoscope And Accessories, Flexible/Rigid  
FGA—Kit, Nephroscope

Regulatory Class: Class II

Predicate Device(s): K151084--Well Lead Ureteral Access Sheath  
K150158--Schoelly Cystoscopes/ Hysteroscopes And  
Accessories  
K151308—Schoelly Nephroscope Set

## 1. Intended 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 the endoscopic procedures.

## 2. Device Description

The ClearPetra Suction-Evacuation Sheath is designed to establish a conduit for the treatment of urinary stones or other urinary diseases during the endoscopic procedures. The intended use is for the passage of endoscopes and other urological devices for the purpose of performing diagnostic and surgical procedures such as, nephroscopy, ureteroscopy, or cystoscopy. It is used for the treatment of stones and for the removal of foreign bodies in the urinary tract.

The ClearPetra Suction-Evacuation Sheath comes in three models: ClearPetra Ureteral Access Sheath, ClearPetra Cystoscope Sheath and ClearPetra Nephrostomy Sheath. The Ureteral Access Sheath includes two versions: Access Sheath for the Semi-rigid Ureteroscope and Access Sheath for the Flexible Ureteroscope.

The ClearPetra Suction-Evacuation Sheath is comprised of the following components:

- Sheath
- Obturator
- Luer Connector
- Y Connector
- Rubber Cap

The sheath is fitted with a Y connector on the proximal end. The Y connector is bifurcated: straight tube and oblique tube, The distal straight tube of the ureteral access sheath is reinforced with metal wires for torque resistance.

one segment of the Y connector is straight and is contiguous with the sheath; The other is constructed in an oblique angle with a longitudinal pressure control vent. The oblique tube is to be connected to a negative pressure aspirator with clear tube or alternatively, connected to a specimen collector then onto a negative pressure aspirator, then to collect stones or foreign bodies during the endoscopic procedure.

An obturator is included for the insertion of the sheath. The obturator is radiopaque and is fitted with a luer connector on the proximal end. 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 device is offered in French size ranging from 10Fr to 22Fr and length 13cm to 55cm. The device is composed of biologically safe materials. It is supplied sterile and intended for single use only.

### 3. Substantial Equivalence—Comparison to Predicate Devices

#### ※ Similarities Between Proposed and Predicate Devices

ClearPetra Suction-Evacuation Sheath, comes in three models: ClearPetra Ureteral Access Sheath, ClearPetra Cystoscope Sheath and ClearPetra Nephrostomy Sheath and the predicate devices, Well Lead Ureteral Access Sheath, Schoelly Cystoscopes/ Hysteroscopes And Accessories, Schoelly Nephroscope Set, Schoelly Ultra-Mini Nephroscope Set, have the same intended use, principle of operation, patient population, performance characteristics and technological characteristics.

#### ※ Differences Between Proposed and Predicate Devices

The differences between proposed and predicate devices, as shown in the following:

- ① The proposed device comes in three model: ClearPetra Ureteral Access Sheath, ClearPetra Cystoscope Sheath and ClearPetra Nephrostomy Sheath. Its predicate devices come from three independent submission. The indications for Use for the proposed ClearPetra Suction-Evacuation Sheath comprises a subset of the Indications for Use of the predicate Well Lead Ureteral Access Sheath(K151084), predicate Schoelly Cystoscopes/ Hysteroscopes And Accessories(K150158), and predicate Schoelly Nephroscope Set cleared in K151308.

The proposed device is designed to establish a conduit for the treatment of urinary stones or other urinary diseases during the endoscopic procedures. The intended use is for the passage of endoscopes and other urological devices for the purpose of performing diagnostic and surgical procedures such as, nephroscopy, ureteroscopy, or cystoscopy. The three models have the same intended use and principle of operation, so they can be submitted in one submission.

- ② For ClearPetra Ureteral Access Sheath, the only notable difference between its predicate device is the structure of sheath connector. The sheath for proposed device is fitted with a Y connector on the proximal end. The Y connector, it is bifurcated, one segment is straight and is contiguous with the sheath which is to facilitate passage and aid advancement of endoscopes and other urological devices into body for the purpose of performing diagnostic and surgical procedures; The other is oblique and constructed in an oblique angle with a longitudinal pressure control vent. The oblique tube is to be connected to a negative pressure aspirator with clear tube or alternatively, connected to a specimen collector then onto a negative pressure aspirator, then to collect stones or foreign bodies during the endoscopic procedure. It can improved visual field and surgical efficiency. Although they have small difference in design for sheath connector, both of the two sheaths can fit over their inner obturators during application and they both are used to aid in the insertion advancement and removal of endoscopic accessories during endoscopic procedures. They are used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract.

- ③ For ClearPetra Cystoscope Sheath & ClearPetra Nephrostomy Sheath, the notable difference between their predicate devices are the materials, method of sterilization, and components/accessories.

### **Materials**

The proposed ClearPetra Cystoscope/Nephrostomy Sheaths are made from PE and PA disposable materials while the predicate devices are made from reusable stainless steel materials. Although the materials are not identical, but they both are manufactured from materials that meet all the requirements of biocompatibility, the materials in contact were tested as per ISO 10993-1.

### **Method of Sterilization**

The proposed ClearPetra Cystoscope/Nephrostomy Sheaths are sterilized by EO and single use and the predicate devices, Schoelly Cystoscopes/ Hysteroscopes And Accessories and Schoelly Nephroscope Set, are reusable and steam sterilization. Although the sterilization method and reprocessing are not identical, the sterilization validation of ClearPetra has demonstrated that the method of sterilization difference provides equivalent sterility assurance.

### **Components/Accessories**

The proposed ClearPetra Cystoscope/Nephrostomy Sheaths consist only of sheaths and obturators, do not include accessories such as endoscopes(cystoscopes/ hysteroscopes/ nephroscopes), bridges, grasping forceps, etc., the specific examples of uses involving these accessory devices that are present in the predicate indications statement are not included in the indications statement for this submission.

Since the proposed ClearPetra is not intended to be used during hysteroscope procedure, the gynecological surgery is not included in the Indications for Uses for this submission.

Although they have different accessories but the overall structure for Sheath & Obturator two components are similar and they have the same functions. Both the sheaths can fit over their inner obturators during application and they both are used to aid in the insertion advancement and removal of endoscopic accessories during endoscopic procedures. They are used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract .

### **※ Summary and Conclusion**

The ClearPetra Suction-Evacuation Sheath described in this 510(k) has similar technological and performance characteristics to the predicate devices. The proposed device is substantially equivalent in intended use, principle of operation, patient population, performance characteristics and technological characteristics as to predicate devices. The differences in the device do not introduce new issues of safety and efficacy, or raise different questions of safety and effectiveness.

Therefore the proposed ClearPetra Suction-Evacuation Sheath are substantially equivalent to the Well Lead Ureteral Access Sheath(K151084), Schoelly Cystoscopes/ Hysteroscopes And Accessories(K150158), and Schoelly Nephroscope Set cleared in K151308.

#### **4. Summary of Non-Clinical Performance Testing**

The following performance testing was conducted for the ClearPetra Suction-Evacuation Sheath:

- 1) General performance testing including:
  - Connection Strength
  - Bending Resistance
  - Coefficients of Friction
  - Determining the Dimensions

Testing data and results are included in this submission, and demonstrated that the ClearPetra Suction-Evacuation Sheath meets all the pre-determined testing and acceptance criteria.

- 2) Biocompatibility testing as per ISO 10993-1:2009 including:
  - Cytotoxicity as per ISO 10993-5:2009
  - Irritation as per ISO 10993-10:2010
  - Sensitization as per ISO 10993-10:2010
  - Acute Systemic Toxicity as per ISO 10993-11:2006

Biocompatibility testing reports are included in this submission, and demonstrated that the device components that are in contact with the patient are biocompatible.

#### **5. Conclusion**

The ClearPetra Suction-Evacuation Sheath is substantially equivalent to predicate devices Well Lead Ureteral Access Sheath cleared under 510(k) K151084, Schoelly Cystoscopes/ Hysteroscopes And Accessories cleared under 510(k) K150158, and Schoelly Nephroscope Set cleared under 510(k) K151308. Based on the intended use, principle of operation, patient population, performance characteristics, technological characteristics and non-clinical tests performed, the proposed ClearPetra Suction-Evacuation Sheath is substantially equivalent to and as safe and as effective as the legally marketed predicate devices.