DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 12, 2016

JBW7 Innovations, LLC
Jason B. Wynberg, MD
President
17197 Adrian Road
Southfield, MI 48075

Re: K160077
Trade/Device Name: RetroPerc™ Flexible Ureteroscopy-Guided Retrograde Nephrostomy Wire Puncture Set
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LJE
Dated: May 25, 2016
Received: June 1, 2016

Dear Jason B. Wynberg:

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,

Joyce M. Whang -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160077

Device Name
RetroPerc™ Flexible Ureteroscopy-Guided Retrograde Nephrostomy Wire Puncture Set

Indications for Use *(Describe)*
Used to gain precise percutaneous access to the kidney by means of controlled fine wire puncture from within the collecting system. This set and suggested procedure are particularly well-suited for gaining percutaneous access to an unobstructed, non-dilated collecting system when pursuing a planned course of endourological intervention. Fluoroscopic control is necessary throughout this procedure. Intended for one-time use.

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.

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510(k) Summary

Sponsor: JBW7 Innovation, LLC

Contact Person: Jason B. Wynberg, MD

Telephone: 248 996 2775

Email: jbw7innovations@gmail.com

Submission Date: January 12, 2016

Device Name: RetroPerc™ Flexible Ureteroscopy-Guided Retrograde Nephrostomy Wire Puncture Set

Common Name: RetroPerc™ Wire Puncture Set

Classification

Regulatory Class:	Unclassified
Product Code:	LJE
Classification Panel:	None

Legally Marketed Predicate Device: Lawson Retrograde Nephrostomy Wire Puncture Set, Cook Medical, K833762

Device Description

The RetroPerc™ Flexible Ureteroscopy-Guided Retrograde Nephrostomy Wire Puncture Set is used to gain precise percutaneous access to the kidney by means of controlled fine wire puncture from within the collecting system. The RetroPerc™ Wire Puncture Set consists of a puncture wire, tip protector sheath with mounted pin-vise actuator, radiopaque exchange catheter, and fascial dilators.

A stainless steel puncture wire is advanced within a protective sheath via the working channel of a flexible ureteroscope positioned in the targeted calyx, at which time the puncture wire is advanced through the kidney, perirenal tissue and fascia, until it emerges at the patient's flank skin. An exchange catheter (coaxial catheter in CX set or single lumen catheter in the LX set) is then positioned over the puncture wire at the flank, after which the puncture wire is removed. A standard 0.038 inch wire guide is then advanced through the exchange catheter until it advances out of the urethra. The exchange catheter is then removed, and finally the tract is dilated with fascial dilators, as clinically indicated. The RetroPerc Wire Puncture Set will be available in two configurations: CX and LX. Each set will perform well for the same patient populations and kidney stones, has the same indications, etc. The choice of set will be driven by physician preference:

the CX set if the surgeon wishes to use a coaxial exchange catheter, and the LX set if the surgeon wishes to use non-coaxial exchange catheter.

Indication for Use

Used to gain precise percutaneous access to the kidney by means of controlled fine wire puncture from within the collecting system. This set and suggested procedure are particularly well-suited for gaining percutaneous access to an unobstructed, non-dilated collecting system when pursuing a planned course of endourological intervention. Fluoroscopic control is necessary throughout this procedure. Intended for one-time use.

Substantial Equivalence

The RetroPerc™ Flexible Ureteroscopy-Guided Retrograde Nephrostomy Wire Puncture Set is substantially equivalent to the predicate device based on the following similarities:

- The indications for use of both predicate and this device are to create a retrograde nephrostomy in the setting of endourological surgery;
- Both devices use a puncture wire that is made of the same material (stainless steel) with a precision grind sharp point;
- Both devices use a tip protector sheath of the same material (TFE) and with similar diameters;
- Both devices use similar wire exchange devices; and
- Both devices are provided sterile for single use.

Comparison of the Lawson Wire Puncture Set (predicate) and the CX and LX Configurations of the RetroPerc™ Wire Puncture Set (this submission).

	Predicate Device COOK® Lawson Wire Puncture Set (K833762)	**RetroPerc™ Wire Puncture Set - CX This Submission**	**RetroPerc™ Wire Puncture Set -LX This Submission**
Intended Use	A nephrostomy puncture set to establish a nephrostomy tract in the setting of endourological surgery.	A nephrostomy puncture set to establish a nephrostomy tract in the setting of endourological surgery.	A nephrostomy puncture set to establish a nephrostomy tract in the setting of endourological surgery.
Indications for Use	This set is intended to gain precise percutaneous access to the kidney	This set is intended to gain precise percutaneous access to the kidney	This set is intended to gain precise percutaneous access to the kidney

	by directing a fine puncture wire through a fluoroscopically directed catheter that has been carefully positioned at the papilla of a selected renal calyx. This is performed while pursuing a planned course of endourological interventions.	by directing a fine puncture wire through a fluoroscopically directed catheter that has been carefully positioned at the papilla of a selected renal calyx. This is performed while pursuing a planned course of endourological interventions.	by directing a fine puncture wire through a fluoroscopically directed catheter that has been carefully positioned at the papilla of a selected renal calyx. This is performed while pursuing a planned course of endourological interventions.
Target Population	Patients requiring percutaneous nephrostomy creation in the setting of endourological surgery.	Patients requiring percutaneous nephrostomy creation in the setting of endourological surgery.	Patients requiring percutaneous nephrostomy creation in the setting of endourological surgery.
Where performed	Operating room	Operating room	Operating room
Anatomical Site	Kidney	Kidney	Kidney
Surgical Technique	Puncture is retrograde through the kidney and out the flank	Puncture is retrograde through the kidney and out the flank	Puncture is retrograde through the kidney and out the flank
Patient Position at the time of the Procedure	Modified lithotomy position, with flank slightly elevated[1,2]	Modified lithotomy position, with flank slightly elevated[3]	Modified lithotomy position, with flank slightly elevated[3]
Method of targeting calyx for puncture	Fluoroscopy	Fluoroscopy + Visual from an indwelling ureteroscope	Fluoroscopy + Visual from an indwelling ureteroscope
Components of the Set	3 Fr sheath 0.017 inch puncture wire 7 Fr Torcon catheter, 0.045 inch deflecting wire guide	2.7 Fr sheath, 0.0174 inch puncture wire (flexible ureteroscope serves steering / targeting function)	2.6 Fr sheath 0.0175 inch puncture wire (flexible ureteroscope serves steering /targeting function)

	22 ga & 18 ga coaxial needles for wire exchange 0.038 inch wire guide	5 Fr coaxial catheter for wire exchange 6, 8 & 10 Fr fascial dilators	5 Fr single lumen catheter for wire exchange 6, 8, & 10 Fr fascial dilators
Puncture wire	Stainless steel; puncture point is ground to be sharp for puncture	Stainless steel; puncture point is ground to be sharp for puncture	Stainless steel; puncture point is ground to be sharp for puncture
Puncture wire length	130 cm	163 cm	190 cm
Puncture wire – diameter of distal 29 cm (puncture segment)	0.017 inch	0.0174 inch	0.0175 inch
Puncture wire – diameter of proximal wire (proximal to distal 29 cm)	0.017 inch	0.020 inch	0.0175 inch
Wire Tip Protector Sheath	TFE construction	TFE construction	TFE construction
Length of TFE tip protector Sheath	85 cm	90 cm	150 cm
Outer diameter of TFE wire protector sheath	3 French	2.7 French	2.6 French
Puncture wire exchange system	22 gauge needle cannula advanced over 0.017 inch wire at flank. Then, 18 gauge needle cannula advanced over 22 gauge needle.	30 cm 5 French coaxial microintroducer, advanced over 0.020 inch puncture wire at flank	32 cm 5 French single lumen polyethylene catheter, advanced over 0.0175 inch wire and TFE sheath at flank
Accessories	Wire guide - 0.038 inch	Fascial Dilators 17.8 cm; 6, 8, 10 French, polyethylene, with $BaSO_4$	Fascial Dilators 17.8 cm; 6, 8, 10 French, polyethylene, with $BaSO_4$
Packaging	Thermoformed tray	Protective plastic tubing secured with	Protective plastic tubing secured with

	Sealed Tyvek/Poly Mylar peel pack package. Accessories sealed in separate Tyvek/Poly Mylar peel pack, contained inside main Tyvek/Mylar peel pack.	indented tabs Sealed Tyvek/Poly Mylar peel pack package Accessories sealed in separate Tyvek/Poly Mylar peel pack, contained inside main Tyvek/Mylar peel pack. 5 sterilized, packaged devices stored and shipped inside a single sealed cardboard box.	indented tabs Sealed Tyvek/Poly Mylar peel pack package Accessories sealed in separate Tyvek/Poly Mylar peel pack, contained inside main Tyvek/Mylar peel pack. 5 sterilized, packaged devices stored and shipped inside a single sealed cardboard box
Sterilization	Exposure to ethylene oxide (EO)	Exposure to ethylene oxide (EO)	Exposure to ethylene oxide (EO)
Re-Use	Single use, disposable	Single use, disposable	Single use, disposable
Tissue Contact Materials	Compliant with ISO 10993	Compliant with ISO 10993	Compliant with ISO 10993

REFERENCES (re: "Patient position at the time of the procedure")

1. Al-Otaibi KM. Retrograde upper-pole calyceal access for percutaneous nephrolithotripsy of stones in the lower-pole calyx. *Arab J Urol* 2012; 10(4): 353-357.

2. Sivalingham S, *et al*. Percutaneous nephrolithotomy with retrograde nephrostomy access: a forgotten technique revisited. *J Urol* 2013; 189(5): 1753-1756.

3. Wynberg JB. Flexible ureteroscopy-directed retrograde nephrostomy for percutaneous nephrolithotomy: description of a technique. *J Endourol* 2012; 26(10): 1268-1274.

The RetroPerc™ Wire Puncture Set has the same intended use and comparable technological characteristics as the predicate device. The RetroPerc Wire Puncture Set exhibits many of the same design features and materials of construction as the predicate device. Any differences in technological characteristics between the RetroPerc™ device and the Lawson wire puncture set do not raise any new safety or effectiveness questions. In addition, accepted scientific methods exist for assessing the effect of these new

characteristics. Performance (bench) and biological safety (biocompatibility) testing demonstrate that the functionality, integrity, and safety of the RetroPerc Wire Puncture Set are adequate for its intended use and support a determination of substantial equivalence to the marketed predicate device.

Performance Data

Bench testing was conducted on the device to assess mechanical and dimensional attributes tested, such as the insertion/extraction forces through the working channel of a ureteroscope and simulated tissue and dimensional analyses, indicate that there are no new safety and efficacy questions raised by the design and, when compared to the predicate device, were equivalent.

In addition, bench testing was conducted to verify that the RetroPerc™ Wire Puncture Set is compliant with biocompatibility requirements for a short duration indwelling device (≤ 24 hours) as specified in ISO 10993 - Part 1. Due to its labeling as sterile, the device underwent sterilization validation and shelf life testing to confirm the label shelf life and are in compliance with the following:

ISO 10555-1:2013 Intravascular catheters -- Sterile and single-use catheters -- Part 1: General requirements

ISO 11135-1 Sterilization of health care products – Ethylene oxide -Part 1: Requirements for development, validation and routine control of a sterilization process for medical device;

Conclusion

The RetroPerc™ Flexible Ureteroscopy-Guided Retrograde Nephrostomy Wire Puncture Set and the predicate Lawson Retrograde Nephrostomy Wire Puncture Set have the same intended use, indications for use, and have equivalent characteristics. Furthermore, the minor differences between the RetroPerc™ Wire Puncture Set and the predicate device raise no new questions of safety or effectiveness.