August 2, 2023

YouCare Technology Co., Ltd. (Wuhan)
Bing Hu
Manager
Tangxunhu North Street
Wuhan, Hubei 430000
China

Re: K230748
Trade/Device Name: Disposable Ureteral Access Sheath
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FED
Dated: July 5, 2023
Received: July 5, 2023

Dear Bing Hu:

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 -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
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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)*
K230748

Device Name
Disposable Ureteral Access Sheath

Indications for Use *(Describe)*
The Disposable 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.

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YouCare Technology Co., Ltd.(Wuhan).

Section 5 - 510(k) Summary

Date of Summary Preparation: 07/16/2023

1. Submitter's Identifications

Submitter's Name: YouCare Technology Co., Ltd.(Wuhan).
Address: Great Wall Science and Technology Park, Tangxunhu North Street，East Lake Development Zone Wuhan，430223 Hubei P.R. China.
Contact Person: Bing Hu
Contact Email: hb@youcaretech.com
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2. Correspondent's Identifications

Correspondent's Name: YouCare Technology Co., Ltd.(Wuhan).
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Contact Person: Bing Hu
Contact Email: hb@youcaretech.com
Telephone: +86-27-87926396-830

3. Name of the Device

Product Name: Disposable Ureteral Access Sheath
Trade Name: Disposable Ureteral Access Sheath
Model:
YC-Videoaid-sheath-A
YC-Videoaid-sheath-B
Classification Name: Endoscope and accessories
Regulation Number: 21 CFR§ 876.1500
Product Code: FED
Device Classification: Class II

4. The Predicate Devices

K151084

Well Lead Ureteral Access Sheath

This predicate has not been subject to a design-related recall.
No reference devices were used in this submission

5. Device Description

The product is composed of sheath tube, sheath tube base, dilator and center base of dilator. The sheath tube base contains a backwater interface. The center base of dilator consists of upper cover of dilator base, lower cover of dilator base , fiber image channel interface F, irrigation channel interface I, equipment channel interface E, obturator, two-way water valve, needle free joint. There is no guide wire. The product is sterilized by EO, it should be sterile and only for

single use.

6. Indications for use

The Disposable 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.

7. Operating instructions

1. Check the package, it is forbidden to use when sterile barrier is damaged.
2. Open the package, and make sure that the product structure is complete without missing of product structure, and it is firmly connected between two-way water valve and irrigation channel, obturator and fiber image channel, needle free joint and equipment channel
3. Insert the guide wire (diameter no more than 0.035 inch or 0.89mm) into ureter to the predetermined length, and then build the channel.
4. The endoscope is inserted through the obturator into the fiber image channel until the objective lens of endoscope reaches the end of the dilator. Connect the negative pressure aspirator to irrigation channel.
5. After flushing and lubricating the sheath tube with normal saline, take away the needle free joint, insert the guide wire into the channel (marked with a notch) on the top of dilator which until it extends out of the equipment channel interface E, then reinstall the needle free joint after threading guide wire out of the needle free joint..
6. Push the dilator/sheath along guide wire, open the two-way water valve and water irrigation system to ensure the view of the endoscope is clear. Confirm the position of dilator/sheath through the endoscope.
7. Fix the sheath in place, at the same time, loosen the joint and remove the dilator.
8. Import the required endoscope or other surgical instruments.

8. Substantial Equivalence

Comparison of technology characteristics

	New device	Predicate device	Comparison
"K"NUMBERS	/	K151084	/
Manufacturer	YouCare Technology Co., Ltd.(Wuhan).	Well Lead Medical Co. Ltd	/
Regulation #	876.1500	876.1500	Same
Product Code	FED	FED	Same

Classification name	Endoscope and accessories	Endoscope and accessories	Same
Intended use	It is intended to establish a channel during urologic surgical procedures, facilitating the passage of endoscopes and other instruments into the urinary tract.	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.	Same
Regulatory Class	Class II	Class II	Same
Sterility	Yes	Yes	Same
Sterilization Method	EO	EO	Same
Single Use	Yes	Yes	Same
Sheath ID	12Fr	10Fr，12Fr，14Fr	Different 1
Sheath length	45cm，35cm	13cm, 20cm, 28cm, 35cm, 45cm, 55cm	Different 2
Primary structure	The product is composed of sheath tube, sheath tube base, dilator and center base of dilator. The sheath tube base contains a backwater interface. The center base of dilator consists of upper cover of dilator base, lower cover of dilator base , fiber image channel interface F, irrigation channel interface I, equipment channel interface E, obturator, two-way water valve, needle free joint.	The Well Lead Ureteral Access Sheath is comprised of three components: sheath, dilator and connector. The outer surface of the sheath has a hydrophilic coating.	Different 3
Materials	**sheath tube:**Pebax6333 SA01 MED, SUS 304、 PTFE、PAM **sheath tube base:** ABS, PC (backwater interface: PC) **dilator**: LDPE	**Sheath Tube:** PTFE、Nylon（PA）、stainless steel **Outer surface：** Nylon（PA） **Inner surface：** PTFE **Dilator：** Polyethylene（PE）	Different 4

	center base of dilator **upper cover of the dilator base:** ABS **lower cover of the dilator base:** ABS **fiber image channel interface F:** PC **irrigation channel interface I:** PC **equipment channel interface E:** PC **obturator:** PC, silica gel **two-way water valve:** PC, POM **needle-free joint:** PC, silica gel		
Package	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Same
Biocompatible	Yes	Yes	Same
Shelf Life	3 years	3 years	Same
Bending Resistance	Bending any section of the dilator, sheath tube or the assembly of sheath tube and dilator into a ring with a radius of 5cm for 1min, there should be no crease, crack or other undesirable phenomena.	Bending any section of the dilator, sheath tube or the assembly of sheath tube and dilator into a ring with a radius of 5cm for 1min, there should be no crease, crack or other undesirable phenomena.	Same
Coefficients of Friction	When the sheath tube is tested for friction, the friction coefficient shall not exceed 0.03.	When the sheath tube is tested for friction, the friction coefficient shall not exceed 0.03.	Same
Peak tensile force	The peak tensile force of the sheath tube and dilator should not be less than 15N. And the peak tensile force of the junction between sheath tube and sheath tube base, the dilator and center base of dilator also shall meet the requirement.	The Dilator to Hub Tensile Strength>15N.	Same

9. Substantial equivalence discussion:

Different 1 –sheath ID

This difference is in sheath ID. Different sheath inner diameter device will be selected by physician per patient's condition. Moreover, a small diameter difference has little effect on the product safety performance

Different 2 –Sheath length

This difference is in sheath length. Different sheath length device will be selected by physician per patient's condition, the length difference did not affect the safety and efficacy of the product.

Different 3 - Primary structure

The sheath base of the new device is similar to the connector of the predict product. The New device has three instrument channels--- image channel, irrigation channel and equipment channel, it does not raise different questions of safety and effectiveness for patient, it only increases the operation requirements for doctors.

Different 4 - Materials

The materials of sheath tube and dilator are different. The new device is 304 Stainless Steel and Pebax6333 and Low-Density Polyethylene(LDPE), the materials of predicate device is Stainless Steel、Nylon(PA)and Polyethylene. Pebax6333 is a block polymer composed of nylon and polyether parts, which has the properties of nylon. Although the materials are different, the performance of the product is not affected, and both passed the biological test.

Substantial Equivalence discussion:

The proposed devices and the predicated device have the same classification information, similar materials, same specifications, same performance effectiveness. The Model of Proposed Device is included in the Model of Predicate device. The Indications for use of proposed device is same as the predicated device. the proposed devices are as safe, as effective and perform as well as the predicate device. So the proposed devices are Substantially Equivalent (SE) to the predicate device which is US legally market device.

10. Non-Clinical Tests Performed:

Non-clinical Testing: A series of preclinical tests were performed to assess the safety and performance of the Disposable Ureteral Access Sheath including biocompatibility physical and mechanical performance.

The following biocompatibility and safety tests were conducted in compliance with ISO standards:

Biocompatibility

- Cytotoxicity Test: ISO10993-5
- Sensitization: ISO 10993-10
- Intracutaneous reactivity:1SO10993-10

- Material mediated pyrogenicity: ISO10993-11
- Acute systemic toxicity: ISO10993-11

Ethylene Oxide Sterilization Validation:

- ISO 11135:2014
- ISO 11737-1:2018
- ISO11737-2:2019
- ISO 10993-7: 2008

Shelf life and Package Validation:

- ASTM F1980-2016
- ASTM D3078-02-2021
- ASTMF 1929-15
- ASTM F88/F88M-15

11. Performance testing

The following performance testing was conducted:

- Bending resistance
- Coefficients of Friction
- Determining the Dimensions
- Flow test
- Patency
- Connection
- Peak tensile force
- Luer taper

12. Clinical Test Conclusion

No clinical study is included in this submission.

13. Conclusion:

Comparison to the predicate devices for Intended Use, structure and physical, it shows that our products are as safe, as effective and performs as well as the predicate devices.

--- End of this section ---