April 30, 2021

Suzhou Beyo Medical Technology Co., Ltd.
Aline Qin
Supervisor of Quality Department
No. 38 Beiguandu Road
Suzhou, Jiangsu 215000
China

Re: K203165
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: March 29, 2021
Received: April 5, 2021

Dear Aline Qin:

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,

for 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
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)*
K203165

Device Name
Disposable Ureteral Access Sheath

Indications for Use *(Describe)*
The Ureteral Access Sheath is intended to use in urologic endoscopic procedures to facilitate the passage of endoscopes.

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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011_Annex 1 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K203165

1. SUBMITTER

Suzhou Beyo Medical Technology Co., Ltd.

2nd Floor, 5th Building, No.38 Beiguandu Road, Wuzhong District, 215000 Suzhou, P.R.China

Phone: +86-512-67269209

Contact Person: Aline Qin

Contact title: Supervisor of Quality Department

Mail: qinling@beyomed.com

Date Prepared: March 29, 2021

2. DEVICE

Name of Device: Disposable Ureteral Access Sheath
Common or Usual Name: Disposable Ureteral Access Sheath
Classification Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED
Model Number: BY-AS-1025, BY-AS-1035, BY-AS-1040, BY-AS-1045, BY-AS-1055, BY-AS-1225, BY-AS-1235, BY-AS-1240, BY-AS-1245, BY-AS-1255, BY-AS-1425, BY-AS-1435, BY-AS-1440, BY-AS-1445, BY-AS-1455.

3. PREDICATE DEVICE

Product Name: *Well Lead Ureteral Access Sheath*

510(k) Number: K151084

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

4. DEVICE DESCRIPTION

The Disposable Ureteral Access Sheath is one single use device, which is provided after EO sterilization. The shelf life of Disposable Ureteral Access Sheath is 3(three) years.

The Disposable Ureteral Access Sheath consists of two major components: sheath assembly

and dilator assembly. Sheath assembly consists of sheath and sheath hub, the dilator assembly consists of dilator, dilator hub and dilator clip. And there is a hydrophilic coating on the surface of the sheath and dilator.

The Disposable Ureteral Access Sheath is designed to provide the physician with reliable access to the urinary tract, the ability to inject fluids, and act as a conduit for device changes. Like all ureteral access sheath sets, Beyo's Disposable Ureteral Access Sheath also protects the ureter during device exchanges, thus helping reduce tissue trauma. Both the dilator and sheath are radiopaque and have a lubricous hydrophilic coating.

To guide the access sheath into the body orifice, the dilator is advanced over up to a 0.038" guidewire. The device can be visualized under X-ray(fluoroscopy) during placement to confirm location. The device can accept other urological instruments with OD's compatible with the sheath's OD of 10,12 and 14 Fr.

The device has two assemblies, sheath assembly and dilator assembly, the two assemblies are combined through dilator clip, the dilator can insert and withdrawn easily from sheath, The dilator assembly can be fixed on the sheath assembly.

5. INDICATIONS FOR USE

The Ureteral Access Sheath is intended to use in urologic endoscopic procedures to facilitate the passage of endoscopes.

6. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

According to ISO 10993-1:2009 Table A.1 –Evaluation tests for consideration and the intended use, the Disposable Ureteral Access Sheath is categorized as a surface device that contacts with mucosal membrane only, limited exposure. The biological safety tests recommended in ISO 10993-1:2009 for this category of devices are: cytotoxicity; irritation and sensitization.

The biological safety of the Disposable Ureteral Access Sheath has been evaluated in accordance with the requirements of ISO 10993-1:2009. The Disposable Ureteral Access Sheath contacts the human body component is sheath, dilator and hydrophilic coating and the material is summarized as below table 1.

Table 1 Patient Contact Material Identification

NO.	Contact human body component name	Material		Duration of contact	Nature of body contact
1	Sheath	PEBAX+SUS+PTFE		<24hrs	Ureter
2	Dilator	LDPE		<24hrs	Ureter
3	Hydrophilic coating	Primer Coating	Polyurethane + deionized water mixture	<24hrs	Ureter
		Top Coating	Polyacrylamide + isopropanol + deionized water mixture		

Animal Study

This section is not applicable to the proposed device, because there is no animal testing of this device.

Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.

The test results demonstrated that the proposed device complies with the following standards:

No.	Standard Name	Title of Standard
1	EN 1618:1997	Catheters other than intravascular catheters-Test methods for common properties.

Clinical Test Conclusion

No clinical study is included in this submission.

7. Substantially Equivalent (SE) Comparison

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Table 1 Comparison of Technology Characteristics

Item	Proposed Device Disposable Ureteral Access Sheath	Predicate Device Well Lead Ureteral Access Sheath (K151084)	Substantial Equivalence
Product Code	FED	FED	Same
Regulation No.	876.1500	876.1500	Same
Class	II	II	Same
Supplied Sterile	Yes	Yes	Same
Sheath ID	10Fr, 12 Fr, 14Fr	10Fr, 12 Fr, 14Fr	Same
Sheath Effective Length	25cm, 35cm, 40cm, 45cm, 55cm,	13cm, 20cm, 28cm, 35cm, 45cm, 55cm	Similar
Indications for Use	The Ureteral Access Sheath is intended to use in urologic endoscopic procedures to facilitate the passage of endoscopes.	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.	Similar
Configuration	Sheath, sheath hub, dilator, dilator hub, dilator clip, hydrophilic coating	sheath, dilator, connector, hydrophilic coating	Similar
Single Use	Yes	Yes	Same
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Same
Shelf Life	Three years （36 months）	Three years （36 months）	Same

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Table 2 Comparison of Performance testing

NO.	Characteristics	Specifications	Test method	Standard	Comparison Result
1	Dimensions	Dimension of ureteral access sheath shall comply with the requirements of Table 3 Dimensions.	Using a universal gage.	Internal requirement	SE
2	Dilator & Sheath Compatibility	The dilator should be able to enter and withdraw smoothly and unobstructed within the sheath.	Pull the dilator out of the sheath, then insert it into the sheath cavity, repeat three times, the results should meet the requirements.	Internal requirement	SE
3	Hub security	Dilator hub can lock onto the sheath hub, dilator can be fixed on the sheath hub, no relative slip.	The dilator hub is screwed off from the sheath hub and then inserted into the sheath in the same direction. The results should meet the requirements.	Internal requirement	SE
4	Sheath Inner Lumen Passability	The dilator should be able to pass through the sheath with a minimum bending radius of 55 mm.	The sheath is bent under the condition that the marking length is 55 mm, the dilator pass through the sheath inner cavity, the results should meet the requirements.	Internal Requirement	SE
5	Dynamic Friction Force	The surface dynamic friction of the sheath after water contact should be <0.5N.	Soaking the samples with the distilled water, use the Automatic friction tester, set the grip force 200g force, speed 200mm/min, distance 15mm.Back and forth 10 times, the results should meet the requirements.	Internal requirement and clinical requirement.	SE

6	Dilator to Hub Tensile Strength	The Dilator to Hub Tensile Strength≥15N.	Cut out a 5cm sample from the dilator (with hub part) ; place the sample on the clamp of the tension machine and clamp it. Set the standard distance as 20mm and the tensile speed as 400mm/min. Run the tension machine to test and record the maximum force value when the product breaks.	EN1618:1997	SE
7	Sheath to Hub Tensile Strength	The Sheath to Hub Tensile Strength≥15N.	Cut out a 5cm sample from the sheath (with hub part); place the sample on the clamp of the tension machine and clamp it. Set the standard distance as 20mm and the tensile speed as 400mm/min. Run the tension machine to test and record the maximum force value when the product breaks.	EN1618:1997	SE
8	Guidewire compatibility	0.038” (0.97mm) guidewire can smoothly enter and exit the inner cavity of the dilator.	Inject liquid and simulate the medical guidewire lumen to verify that it can pass smoothly.	Internal requirement	SE
9	Sheath Flexibility	Sheath &Dilator should be flexible, when the tip bending 90°，the sheath and dilator can recover，when bending 10 times with a minimum bending radius of 55 mm, the sheath and dilator can not kink or broken.	Fix the sheath and dilator tip, rotate the hub 90°，the sheath and dilator should not permanent deformation, after the sheath and dilator recover, bending 10 times with a minimum bending radius of 55 mm, the results should meet the requirements.	Internal Requirement	SE

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10	Sheath Bending Resistance	The bending force should more than 2.1N，less than 7.6N.	Cutting 25cm samples from the distal end of sheath, set the sample into the tensile machine fixture with vertical direction, set the speed 10mm/min, fix the samples, compressed down 3cm.The results should meet the requirements.	Internal Requirement	SE

8. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis from the nonclinical tests, the proposed devices is safe and effective, the performance is as well as the predicate devices. It is determined to be Substantially Equivalent (SE) to the predicate devices.