May 25, 2022

Zhejiang Chuangxiang Medical Technology Co., Ltd.
Lucius Long
RA Manager
Room 101,201,301,401,501, Building 50, No.650
Hongfeng Road Donghu Street, Yuhang District
Hangzhou, Zhejiang Province 311100
China

Re: K220065
Trade/Device Name: Single Use Ureteral Access Sheath
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FED
Dated: April 27, 2022
Received: May 3, 2022

Dear Lucius Long:

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)*
K220065

Device Name
Single Use Ureteral Access Sheath

Indications for Use *(Describe)*
The device 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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Zhejiang Chuangxiang Medical Technology Co., LTD.

Section 5 510(k) Summary(21CFR 807.92)

1. Submitter's information

Name: Zhejiang Chuangxiang Medical Technology Co., LTD.
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Fax: 86-571-89167086

2. Date of Submission

27-Dec- 2021

3. Device

Trade/Device Name: Single Use Ureteral Access Sheath
Regulation name: Endoscope and accessories
Regulation class: II
Regulation number: 876.1500
Panel: Gastroenterology/Urology
Product code: FED

4. Predicative device

4.1) 510(k) Number: K203165
Device Name: Disposable Ureteral Access Sheath

5. Device description

The Single Use Ureteral Access Sheath is a single use sterile device, provides ureteral dilation and a continuous working channel for the introduction of endoscopes and instruments during ureteral access procedures. The Ureteral Access Sheath is comprised of five components: outer sheath base, outer sheath, dilator tube, locking clip and joint. The outer surface of the sheath has a hydrophilic coating. When activated, the hydrophilic feature allows for easier insertion and removal of the sheath. The sheath is offered in three French sizes: 10Fr, 12Fr and 14Fr, and range in effective length of sheath from 10.0cm (shortest) to 55cm (longest).

The device is packaged in a peel-open pouch with a two-year shelf life.

6. Indications for use

The device is intended to use in urologic endoscopic procedures to facilitate the passage of endoscopes.

7. Comparison of Technological Characteristics:

The Single Use Ureteral Access Sheath has substantially equivalent device design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device Suzhou Beyo's Disposable Ureteral Access Sheath, K203165. The differences between the proposed device and the predicate devices do not raise any questions regarding its safety and effectiveness. The differences are listed in the table below.

Item	Proposed device	Predicate device	Comparison to Predicate Devices
Device name	Single Use Ureteral Access Sheath	Disposable Ureteral Access Sheath	/
Product code	FED	FED	Same
Regulation No.	876.1500	876.1500	Same
Class	II	II	Same
Indications for Use	The device is intended to use in urologic endoscopic procedures to facilitate the passage of endoscopes.	The Ureteral Access Sheath is intended to use in urologic endoscopic procedures to facilitate the passage of endoscopes.	Same
Configuration	Dilator tube, Outer sheath, Outer sheath base, Joint, Locking clip hydrophilic coating	Sheath, sheath hub, dilator, dilator hub, dilator clip, hydrophilic coating	Same
Sheath ID	10Fr, 12Fr, 14Fr	10Fr, 12Fr, 14Fr	Same
Sheath Effective Length	10.0cm, 16.5cm, 20cm, 25cm, 35cm, 45cm, 55cm	25cm, 35cm, 40cm, 45cm, 55cm	Similar
Supplied Sterile	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	Two years (24 months)	Three years (36 months)	Similar

8. Applicable Guidance Document

NA

9. Performance Data

The following bench tests were performed on Single Use Ureteral Access Sheath: Appearance, Dimension, Physical properties. The results of all testing were passing.

The EO residual was measured after sterilization of the device to meet the criteria defined in ISO 11135 Second edition 2014-07-15"Sterilization of Health Care products Ethylene Oxide - Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices [Including: Amendment 1 (2018)]", and ISO 10993-7 Second Edition 2008-10-15 "Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]".

The shelf-life for two years had been validated in accelerated testing according to ASTM F1980-16 (2016) and the requirements on packaging for terminally sterilized medical device per ISO 11607-1 Second Edition 2019-02 and ISO 11607-2 Second Edition 2019-02 are also met. The testing successfully demonstrated essential performance is achieved before and after the shelf life test.

Biocompatibility testing was performed to show that all patient contacting materials meet applicable biocompatibility standards per ISO 10993-1:2009 and the FDA guidance: Use of International Standard ISO 10993-1 "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process". The cytotoxicity, sensitization and intracutaneous reactivity were performed to ensure the biocompatibility of the subject device set.

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusions

Chuangxiang medical has been demonstrated that the proposed device Single Use Ureteral Access Sheath is substantially equivalent to Suzhou Beyo Medical Technology Co., Ltd. currently marketed Disposable Ureteral Access Sheath (K203165).