June 4, 2018

Changzhou Rongxin Medicine Minimal Invasion Technology Co., Ltd.
℅ Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
8-9th Floor, R&D Building, No. 26 Qinglan Street Panyu District
Guangzhou, 510006
CHINA

Re: K172807
Trade/Device Name: Silicone Foley Catheter for Single Use
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: EZL
Dated: May 4, 2018
Received: May 4, 2018

Dear Mike Gu:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

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 on last page.

510(k) Number *(if known)*

K172807

Device Name
Silicone Foley Catheter for single use

Indications for Use *(Describe)*
Two-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage and urological use only; the indwelling time is no more than 30 days.
Three-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage and bladder irrigation for urological use only; the indwelling time is no more than 30 days.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

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

1. SUBMITTER

CHANGZHOU RONGXIN MEDICINE MINIMAL INVASION TECHNOLOGY CO., LTD.
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Secondary Contact Person:	Ping Liu Quality Assurance Manager CHANGZHOU RONGXIN MEDICINE MINIMAL INVASION TECHNOLOGY CO., LTD. Tel: +86-0519-82446628 Fax: +86-0519-82446610
Date prepared	May 3, 2018

2. DEVICE

Device Name:	Silicone Foley Catheter for single use
Common/Usual Name:	Silicone Foley Catheter for single use
Regulation number	21 CFR 876.5130
Regulation Name	Urological catheter and accessories
Regulation Class:	II
Product Code:	EZL
Classification Name	Catheter, Retention Type, Balloon

3. PREDICATE DEVICES

Predicate device: K130908, Disposable Balloon-retention Catheter

These predicates have not been subject to a design-related recall.

4. DEVICE DESCRIPTION

The Silicone Foley Catheter for single use is designed as an intermittent pathway for drainage and irrigation of the bladder. The device is made of silicone. The catheter is provided sterile in a variety of lengths and sizes.

5. INDICATIONS FOR USE

Two-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage for urological use only; the indwelling time is no more than 30 days.
Three-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage and bladder irrigation for urological use only; the indwelling time is no more than 30 days.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Specification	**Predicate Device**	**Proposed Device**	**Discussion of Differences**
Device name	Disposable Balloon-retention Catheter	Silicone Foley Catheter for single use	similar
K number	K130908	——	
Indications for use	Two-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage and urological use only; the indwelling time is no more than 30 days. Three-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage and bladder irrigation for urological use only; the indwelling time is no more than 30 days.	Two-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage and urological use only; the indwelling time is no more than 30 days. Three-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage and bladder irrigation for urological use only; the indwelling time is no more than 30 days.	Identical

Specification	Predicate Device	Proposed Device	Discussion of Differences
Intended population	Pediatric ,male and female	Pediatric ,male and female	Identical
Anatomical Sites	Urethra, bladder	Urethra, bladder	Identical
Lumen	Two way, three way	Two way, three way	Identical
Size range	6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr, 26Fr	6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr	
Tube Length	6Fr, 8Fr ,10Fr: 310mm 12Fr-26Fr: 400mm	6Fr, 8Fr ,10Fr: 310mm 12Fr-24Fr: 400mm	Identical
Balloon	Yes	Yes	Identical
Balloon size	1.5ml, 3ml, 5ml, 10ml, 15ml, 20ml, 30ml	3ml, 5ml, 10ml, 15ml, 30ml	Identical
Eyes in tip	Two-way: no Three-way: yes	Two-way: no Three-way: yes	Identical
Tip shape	circular	circular	Identical
Standard funnel	Yes	Yes	Identical
Steel wire in pediatric models	yes	yes	Identical
Material of main shaft	silicone	silicone	Identical
Single use	Yes	Yes	Identical
Shelf life	3 years	3 years	Identical
Sterility	EO	EO	Identical

Silicone Foley Catheter for single use is substantially equivalent to the cleared predicate device, Disposable Balloon-retention Catheter (K130908) because it has same indications for use, is composed of the same materials, and has similar technological characteristics.

7. NON-CLINICAL DATA

The following non-clinical data were provided in support of the substantial equivalence determination.

Performance testing

The device were evaluated according to ASTM F623-99 (2013) and EN 1616:1997. Also, the device was evaluated to be radiopaque in accordance with ASTM F640-2012.

Biocompatibility

According to the guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process",* the following tests have been conducted. Sample preparation and reference materials were conducted based on ISO 10993-12:2012.

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Subchronic Toxicity
- Genotoxicity
- Implantation

Sterility

The device is designed for EO sterilization.

Animal Study

The subject of this premarket submission, Silicone Foley Catheter for single use, does not require animal studies to support substantial equivalence.

8. CLINICAL DATA

The subject of this premarket submission, Silicone Foley Catheter for single use, did not require clinical studies to support substantial equivalence.

9. CONCLUSION

The differences between the Silicone Foley Catheter for single use and its predicate devices do not raise different questions of safety and effectiveness. The non-clinical data support the safety of the device and the performance testing report demonstrate that the Silicone Foley Catheter for single use should perform as intended in the specified use conditions.

From the results of non-clinical data including the performance testing and comparative performance testing described, CHANGZHOU RONGXIN MEDICINE MINIMAL INVASION TECHNOLOGY CO., LTD. concludes that the Silicone Foley Catheter for single use is as safe and as effective as the predicate devices.