April 29, 2022

Bonree Medical Co., Ltd
He Hongbo
General Manager
No.4 Longzhu Garden, Wanmu Industrial Estate, Nanlang
Zhongshan, Guangdong 528451
China

Re: K212430
Trade/Device Name: BONREE Nelaton Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZD, EZC
Dated: March 18, 2022
Received: March 30, 2022

Dear He Hongbo:

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,

Jessica K. Nguyen, Ph.D.
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)*

K212430

Device Name

BONREE Nelaton Catheter

Indications for Use *(Describe)*

The BONREE Nelaton Catheter is used for clean intermittent catheterization (CIC) treatment. It is intended for use by male, female and pediatric patients (2 years old to less than 12 years old) for draining urine from the bladder.

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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510(k) Summary

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

Date:	March 18, 2022
Submitter:	BONREE MEDICAL CO., LTD Address: No.4 Longzhu Garden, Wanmu Industrial Estate, Nanlang, Zhongshan, Guangdong, CN 528451
Contact Person:	He Hongbo General Manager BONREE MEDICAL CO., LTD Email: he@bonreemed.com Tel: +86-760-8520 7588 Fax: +86-760-8520 7568
Device Name:	BONREE Nelaton Catheter
Common Name:	Urological Catheter
Regulation Number:	21 CFR § 876.5130
Regulation Name:	Urological catheter and accessories
Review Panel:	Gastroenterology/Urology
Product Code:	EZD, EZC
Regulatory Class:	Class Ⅱ
Predicate Device(s):	K142575 – Bard RiteCath Intermittent Urinary Catheter

1. Indications for Use

The BONREE Nelaton Catheter is used for clean intermittent catheterization (CIC) treatment. It is intended for use by male, female and pediatric patients (2 years old to less than 12 years old) for draining urine from the bladder.

2. Device Description

The BONREE Nelaton Catheter is sterile, single patient use, urinary drainage catheter that is made from PVC. The catheter is comprised of shaft, tip and funnel. It has two drainage eyes located in the proximal tip and a tapered funnel located at the distal end. The tip is available in a straight or coude configuration. The tip of the catheter passes through the urethra into the bladder to allow urine to drain into the eyelets and then through the catheter shaft, exiting through the funnel.

The BONREE Nelaton Catheters are produced with two different models—Straight Tip and Coude Tip. Both models will be available for male, female and pediatric. The difference between two models is the tip design.

For Straight Tip catheters, the dimensions range from 6Fr to 22Fr which is a range of 2.0 mm to 7.33 mm in Outer Diameter with a straight tip shape.

For Coude Tip catheters, the dimensions range from 10Fr to 18Fr which is a range of 3.33 mm to 6.0 mm in Outer Diameter with a bent catheter tip shape.

The difference between the Female and Male type is the tube lengths. The Male type is offered in a 400mm tube overall length and 370mm tube effective length, whereas the Female type is offered in a 200mm tube overall length and 170mm tube effective length.

Model Number:

Model	Type	Model No.
Straight Tip	Pediatric	30506002 30508002 30510002 30606002 30608002 30610002
	Female	30612002 30614002 30616002 30618002 30620002 30622002
	Male	30512002 30514002 30516002 30518002 30520002 30522002
Coude Tip	Pediatric	30710002 30810002
	Female	30812002 30814002 30816002 30818002
	Male	30712002 30714002 30716002 30718002

The BONREE Nelaton Catheter is composed of biologically safe materials and supplied sterile (sterilized by EO) and intended for single use only.

3. Substantial Equivalence—Comparison to Predicate Device

A side by side comparison of the proposed device and the predicate device are provided below.

Comparison Items	Proposed Device	Predicate Device	Discussion of Differences
Devece Name	BONREE Nelaton Catheter	Bard RiteCath Intermittent Urinary Catheter	---
510k Number	---	K142575	---
Product Code	EZD, EZC	EZD, EZC	Same
Regulation Number	21 CFR § 876.5130	21 CFR § 876.5130	Same
Regulatory Class	Class Ⅱ	Class Ⅱ	Same
Indications for Use/ Intended Use	The BONREE Nelaton Catheter is used for clean intermittent catheterization (CIC) treatment. It is intended for use by male, female and pediatric patients (2 years old to less than 12 years old) for draining urine from the bladder.	The Bard RiteCath Intermittent Urinary Catheter is intended for use by adult and pediatric, male and female patients for draining urine from the bladder. Pediatric patients include neonates, infants, children and adolescents.	Same
Size Range	6Fr-22Fr	6Fr-18Fr	Similar
Materials	Shaft: PVC Funnel: PVC	Shaft: PVC Funnel: PVC	Similar
Design Feature	Consist of shaft, tip and funnel; Have two polished drainage eyes located in the proximal tip for efficient drainage.	Consist of shaft, tip and funnel; Have two polished eyelets located in the proximal tip for efficient drainage.	Same
Tip Configuration	Straight tip Coude tip	Straight tip Coude tip	Similar
Lumen	1-way	1-way	Same
Duration of Use	For intermittent use	For intermittent use	Same
Packing	Peel pack comprises paper and film; Corrugated board inner; Corrugated board outer case.	Peel pack comprises paper and film; Corrugated board inner; Corrugated board outer case.	Same

Supplied Sterile	Yes	Yes	Same
Single Use	Yes	Yes	Same
Sterilization Method	EO sterilized	EO sterilized	Same
Materials Biocompatibility	ISO 10993-1 Cytotoxicity Penile Irritation Sensitization Acute Systemic Toxicity Subchronic Toxicity Pyrogenicity	ISO 10993-1 Cytotoxicity Vaginal Mucosal Irritation Sensitization	Similar

The BONREE Nelaton Catheter described in this 510(k) have similar technological and performance characteristics to the predicate device.
The proposed device has the same classification information, same intended use and technological characteristics as compared to the predicate device. Any difference that exists between the BONREE Nelaton Catheter and the predicate device have no negative effect on safety or effectiveness, or raise different questions of safety and effectiveness. The similarities and differences between the proposed and predicate device have been identified and explained in the comparison matrix which has been included in Section 12 of this submission.

Therefore, the proposed BONREE Nelaton Catheter is substantially equivalent to the legally marketed predicate Bard RiteCath Intermittent Urinary Catheter(K142575). The proposed device has the same classification information, same intended use and technological characteristics as compared to the predicate device.

4. Summary of Non-Clinical Performance Testing

The BONREE Nelaton Catheter has been verified for its safety and effectivity based on the following performance data.

1) Performance Testing

Performance testing was carried out to verify the safety and the effectiveness of the subject device.
Nonclinical functional performance testing was performed in accordance with:

a) ASTM F623-19 — Standard Performance Specification for Foley Catheter
b) ISO 20696:2018 — Sterile urethral catheters for single use

Testing datas and results are included in this submission, and demonstrated that the BONREE Nelaton Catheter meets all the pre-determined testing and acceptance criteria.

2) Biocompatibility

Biocompatibility evaluation for the BONREE Nelaton Catheter was conducted in accordance with:

a) ISO 10993-1:2018 — Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
b) FDA Guidance “Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” published on

The subject device was considered mucosal membrane contacting with prolonged exposure (> 24 hours and up to 30 days). The following tests were performed: Cytotoxicity, Irritation, Sensitization, Acute Systemic Toxicity, Subacute Systemic Toxicity and Pyrogenicity.

Biocompatibility testing reports are included in this submission, and demonstrated that the device componets that are in contact with the patient are biocompatible. All evaluation acceptance criteria were met.

3) Sterilization and Shelf-Life

Sterilization Process has been validated accordance with ISO 11135:2014. The sterility assurance level is SAL 10^{-6}.

Accelerated aging was completed to validate a shelf life of 5 years.

Conclusions Drawn from the Non-Clinical Testing

The results of these tests demonstrate that the device is as safe, as effective, and performs as well as the identified predicates and support a determination of substantial equivalence.

5. Conclusion

The BONREE Nelaton Catheter is substantially equivalent to predicate device Bard RiteCath Intermittent Urinary Catheter(K142575). Based on the intended use, principle of operation, performance characteristics, and technological characteristics, the proposed BONREE Nelaton Catheter is substantially equivalent to and as safe, as effective and performs as the legally marketed predicate device.