November 27, 2019

Hangzhou Bever Medical Devices Co., Ltd.
Ms. Allyson Zhou
Management Representative
Building 2, No. 1-1, Houmuqiao, Yongle Village,
Cangqian St., Yuhang District
Hangzhou, Zhejiang Province 311121
CHINA

Re: K192468
Trade/Device Name: Male, Nelaton-tip Ready-to-Use Hydrophilic Catheter
Female, Nelaton-tip Ready-to-Use Hydrophilic Catheter
Pediatric, Nelaton-tip Ready-to-Use Hydrophilic Catheter
Intermittent Catheter
Male, Tapered-Tip Tiemann Ready-to-Use Hydrophilic Catheter
Male, Olive-Tip Tiemann Ready-to-Use Hydrophilic Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM, EZD
Dated: September 4, 2019
Received: September 9, 2019

Dear Ms. Zhou:

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.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecological, and Urological 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192468

Device Name
Ready-to-Use Hydrophilic Catheter

Indications for Use *(Describe)*

The Ready-to-use Hydrophilic Catheter is indicated for intermittent catheterization of the urethra for those individuals who are unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder -voiding episode. The catheter is inserted into urethra to reach the bladder allowing urine to drain.

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

Date of summary: November 22, 2019

1. Submitter (Owner) of 510 (k):

Hangzhou Bever Medical Devices Co., Ltd.
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Tel：+86-571-8861 6630 Fax：+86-0571-8861 6515
Registration Number: 3008729910

2. Contact person:

Allyson Zhou
Management Representative
Tel：+86-571-8861 6630 Fax：+86-0571-8861 6515
Email: allyson@bevermedical.com

3. Device Name:

Common Name: Catheter, Urethral
Trade Name: Ready-to-use Hydrophilic Catheter
Classification Name: Urological catheter and accessories (21 CFR 876.5130)
Product Code: GBM
Regulation Class: II

4. Legally Marketed predicate(s):

Predicate Device:
SpeediCath - K023254

Reference Device(s):
LoFric® Primo™ - K122078
Self Cath - K100878

5. Device Description

The Ready-to-Use Hydrophilic Catheter is a single use, disposable polyurethane catheter. It is coated and placed in the water, packed and sealed in a foil bag and sterilized. The catheter is prelubricated with a coating containing polyvinylpyrrolidone, which binds the water molecules to the surface of the catheter creating a smooth and even lubricating film.

The Ready-to-Use Hydrophilic Catheter is available for men, women and children, in three different tip configurations of Nelaton (straight and rounded), Tapered (curved and tapered) and Olive (curved and olive), in single or combination with an insertion aid (a sleeve) which provides an easy grip, allowing for insertion without touching. There are two polished drainage eyelets on the catheter in various configurations and types.

The Tiemann catheter has a bended tip along with a guide stripe (in the shaft) and/or aligned with a raised ridge (on the funnel), which will help ensure the catheter tip is still correctly oriented when approaching the bladder.

6. Indications for Use

The Ready-to-Use Hydrophilic Catheter is indicated for intermittent catheterization of the urethra for those individuals who are unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder - voiding episode. The catheter is inserted into urethra to reach the bladder allowing urine to drain.

7. Technological Characteristics

The table below summarizes the technological characteristics of Ready-to-Use Hydrophilic Catheter (subject device) as compared to the legally marketed predicates.

Characteristic	Subject device	Predicate device	Reference device	
	Ready-to-Use Hydrophilic Catheter	SpeediCath K023254	LoFric® Primo™ K122078	Self Cath K100878
Indication for use	Indicated for intermittent catheterization of the urethra for those individuals who are unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder - voiding episode. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.	Indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.	Intended for Intermittent catheterization of the urethra.	Indicated for those individuals unable to promote a natural urine flow or for those individuals who have a significant volume of residual urine following a natural bladder-voiding episode.

Size	Female Fr 6, 8, 10, 12, 14, 16, 18 Male Fr 6, 8, 10, 12, 14, 16, 18 Tiemann Fr 8, 10, 12, 14, 16, 18 Pediatric Fr 6, 8, 10	Female Fr 6, 8, 10, 12, 14, 16 Male Fr 8, 10, 12, 14, 16, 18 Tiemann Fr 10, 12, 14 Pediatric Fr 6, 8, 10 Boy Fr 6, 8, 10, 12	Nelaton 8in Fr 8, 10, 12, 14, 16, 18 Nelaton 16in Fr 8, 10, 12, 14, 16, 18 Tiemann 16in Fr 10, 12, 14, 16, 18 Pediatric 8in Fr 6, 8, 10	Female Fr 8, 10, 12, 14, Male Fr 8, 10, 12, 14, 16, 18 Tiemann Fr 6, 8, 10, 12, 14, 16, 18 Pediatric Fr 5, 6, 8, 10
Device composition	Polyurethane catheter coated with polyvinylpyrrolidone, placed in water, in single or combination with an insertion aid.	Polyurethane catheter coated with polyvinylpyrrolidone, placed in a saline solution containing polyvinylpyrrolidone.	Plastic catheter coated with polyvinylpyrrolidone, packed with the sterile water.	Polyvinyl chloride catheter (without coating)
Condition of use	Singe Use	Singe Use	Singe Use	Singe Use
Coating	PVP(polyvinylpyrrolidone) Based Coating	PVP(polyvinylpyrrolidone) Based Coating	PVP(polyvinylpyrrolidone) Based Coating	No coating
Prelubricated	Yes-by water hydration	Yes-by saline solution hydration	Yes-by water hydration	No
Lubricating solution	Sterile water	Sterile saline solution	Sterile water	No
Ready to use	Yes	Yes	Requires bursting of water packet prior to use	No
No touch design	Yes- contains an insertion aid (sleeve)	No	Yes- by using exterior packaging	No
Tip configuration	Nelaton tip, Tapered tip and Olive tip	Nelaton tip and Tapered tip	Nelaton tip and Tapered tip	Nelaton tip, Tapered tip and Olive tip
Guide stripe in the shaft	Yes- Tiemann Catheter	No	No	Yes- Tiemann Catheter
Drainage Eyelets	Polished and staggered	Polished and staggered	Polished and staggered	Polished and staggered
End Design	Funnel	Funnel	Funnel	Funnel
Duration of use	For intermittent use	For intermittent use	For intermittent use	For intermittent use
Sterile	Yes	Yes	Yes	Yes
Packaging	Peel Pack	Peel Pack	Peel Pack	Peel Pack

8. Summary of Non-Clinical Testing

Performance testing for Ready-to-Use Hydrophilic Catheter was conducted according to applicable sections of voluntary standards:

a) Biocompatibility testing according to ISO 10993-1:2009 and FDA Guidance "Use of International Standard ISO 10993-1" (2016) was completed.

b) Bench testing was completed per ISO 20696, ASTM D 1894 and internal test methods.

Performance testing was conducted according to applicable sections of standards in order to document the following properties of the Ready-to-Use hydrophilic catheter:

- Strength was checked by the test method in Annex A of ISO 20696.
- Connector security was checked by the test method in Annex B of ISO 20696.
- Flow rate was checked by the test method in Annex E of ISO 20696.
- Kink stability was checked by the test method in Annex G of ISO 20696.
- Peak tensile force was checked by the test method in Annex H of ISO 20696.
- Coefficient of friction was checked by the test method in ASTM D 1894.
- Coating adhesion was checked by the test method in BEVER internal methods.

All tests passed.

c) Sterilization validation was conducted according to AAMI/ANSI/ISO 11137-1, AAMI/ANSI/ISO 11137-2 and AAMI/ANSI/ISO 11137-3.

d) Accelerated Aged (in compliance with ASTM F1980) Shelf life testing was completed.

All tests met the pre-determined acceptance criteria.

9. Conclusions

The subject device has the same intended use and similar technological characteristics to the currently-marketed predicate devices. The subject device is substantially equivalent to the currently-marketed predicate devices. Laboratory and safety testing conducted on the product has provided scientific evidence that this subject device is as safe and effective as the predicate device for its intended use.