



January 2, 2026

Jamjoom Fullcare Corporation
% Grace Liu
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, Guangdong 518000
CHINA

Re: K251178
Trade/Device Name: Ready to use Nelaton Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter And Accessories
Regulatory Class: Class II
Product Code: EZD
Dated: December 8, 2025
Received: December 1, 2025

Dear Grace Liu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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

Indications for Use

510(k) Number (if known)
K251178

Device Name
Ready to use Nelaton Catheter

Indications for Use (Describe)

The Ready-to-Use Hydrophilic Catheter is indicated for intermittent catheterization of the urethra for individuals (men, women, pediatrics) who are unable to promote natural urine flow or 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 and ensuring bladder emptying.

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 - K251178

1. Contact Details

1.1 Applicant information

Applicant Name	Jamjoom Fullcare Corporation
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Date Prepared	2025-12-23

1.2 Submission Correspondent

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Phone No.	+86-755-86069197
Contact person	Grace Liu
Contact person's e-mail	grace@cefda.com
Website	http://www.cefda.com

2. Device Information

Trade name	Traditional 510(k)
Trade name	Ready to use Nelaton Catheter
Common name	Catheter, urethral
Classification	II
Classification name	Urological catheter and accessories
Product code	EZD
Regulation No.	21 CFR 876.5130

3. Legally Marketed Predicate Device

Trade Name	Ready-to-use Hydrophilic Catheter
Manufacturer	Hangzhou Bever Medical Devices Co., Ltd.
510(k) Number	K192468
Product Code	GBM
Device Class	II
Regulation No.	21 CFR 876.5130

The predicate device has not been subject to any design-related recall.

4. Device Description

Ready to use Nelaton Catheter is a sterile, single use catheter, intended to be inserted through the urethra to the bladder for intermittent urine drainage. The catheters are available in a variety of lengths and French sizes to accommodate individual anatomy of adult and pediatric patients (including males and females).

The catheter is made of polyurethane, and is not made with PVC. It is prelubricated with a hydrophilic coating. The distal end is either a smooth closed straight or coude tip with two eyelets for efficient drainage. The color-coded funnel at the proximal end can be connected to a urine collection container. There is a gripper on the catheters for adult males (length of 40cm), which serves as protection from the user's touch and aids the user during insertion.

The catheter is sealed in a foil pouch with the hydration liquid (distilled water) in one compartment, so the coated catheter is lubricated by direct contact with the hydration liquid and can be ready to use.

Ready to use Nelaton Catheter is sterilized by E-beam irradiation, and the shelf life is 3 years.

5. Intended Use/Indication for Use

The Ready-to-Use Hydrophilic Catheter is indicated for intermittent catheterization of the urethra for individuals (men, women, pediatrics) who are unable to promote natural urine flow or 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 and ensuring bladder emptying.

6. Substantial Equivalence Comparison

Comparison Item	Proposed Device (K251178)	Predicate Device (K192468)	Comment
Manufacturer	Jamjoom Fullcare Corporation	Hangzhou Bever Medical Devices Co., Ltd.	/
Product Name	Ready to use Nelaton Catheter	Ready-to-use Hydrophilic Catheter	/
Regulation Number	21 CFR 876.5130	21 CFR 876.5130	Same
Classification	Class II	Class II	Same
Prescription Use	Yes	Yes	Same
Single use	Yes	Yes	Same
Ready to use	Yes	Yes	Same
Condition of use	Intermittent catheterization	Intermittent catheterization	Same

Intended Use / Indications for Use		The Ready-to-Use Hydrophilic Catheter is indicated for intermittent catheterization of the urethra for individuals (men, women, pediatrics) who are unable to promote natural urine flow or 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 and ensuring bladder emptying.	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.	Equivalent
Intended patients		Adults and Pediatrics	Adults and Pediatrics	Same
Design	Prelubricated shaft	Yes - by water hydration	Yes - by water hydration	Same
	Tip	Nelaton (straight and rounded); Tapered (curved and tapered)	Nelaton (straight and rounded); Tapered (curved and tapered); Olive (curved and olive)	Equivalent
	Drainage eyelet	2 polished eyelets	2 polished eyelets	Same
	Funnel	Colored funnel	Colored funnel	Same
	No touch design	Gripper	Sleeve	Equivalent
	Guide stripe in the shaft	N/A	Yes for Tiemann catheters	Different than the predicate device
Size		Male, Nelaton: 8, 10, 12, 14, 16, 18 Fr Male, Tiemann: 8, 10, 12, 14, 16, 18 Fr Female: 8, 10, 12, 14, 16, 18 Fr Pediatric male: 6, 8, 10 Fr Pediatric female: 6, 8, 10 Fr	Male: 6, 8, 10, 12, 14, 16, 18 Fr Female: 6, 8, 10, 12, 14, 16, 18 Fr Tiemann: 8, 10, 12, 14, 16, 18 Fr Pediatric: 6, 8, 10 Fr	Equivalent
Materials	Shaft	Polyurethane	Polyurethane	Same
	Hydrophilic coating	Primer coating: Polyurethane Top coating: Polyacrylamide derivatives	PVP (polyvinylpyrrolidone)	Different than the predicate device
	Funnel	Thermoplastic polyurethane	Not publicly available	Equivalent

	Gripper	Polyethylene	Not publicly available	Equivalent
	Hydration liquid	Distilled water	Sterile water	Same
Primary Package		Peel pack	Peel pack	Same
Sterilization		E-beam, SAL 10 ⁻⁶	Radiation, SAL 10 ⁻⁶	Equivalent

In conclusion, Ready to use Nelaton Catheter has the similar indication for use to the predicate device, and also has similar technical characteristics to the predicate device. The differences do not raise different questions of safety and effectiveness.

7. Summary of Non-clinical Testing

Non-clinical tests were conducted to demonstrate the safety and effectiveness of Ready to use Nelaton Catheter and the substantial equivalence to the predicate device.

➤ Performance Testing

The following performance tests were performed on the proposed device according to ISO 20696:2018 and technical specifications:

- Appearance
- Connector security
- Strength
- Flow rate
- Kink stability
- Peak tensile force
- Size (including overall length, effective shaft length and outer diameter)
- Sterility
- Coating properties
- Primary package properties

The test results demonstrate that the proposed device met the requirements of ISO 20696:2018 and technical specifications.

Moreover, coating performance included friction testing and surface dry time testing. Comparative testing between the subject device and the predicate device was conducted using an internal test method. The test results showed that there were no significant statistical differences between them, and they are substantially equivalent in coating performance.

➤ Biocompatibility Testing

The following biocompatibility tests were performed on the proposed device according to FDA guidance - *Use of*

International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued on Sep. 8, 2023, and the test results were acceptable.

- Cytotoxicity per ISO 10993-5:2009
- Vaginal Irritation per ISO 10993-23:2021
- Skin Sensitization per ISO 10993-10:2021
- Acute System Toxicity per ISO 10993-11:2017
- Subacute System Toxicity per ISO 10993-11:2017
- Material-mediated Pyrogenicity per USP <151>

➤ **Sterilization**

A Sterility Assurance Level (SAL) of 10^{-6} was validated in accordance with the requirements of ISO 11137-1:2006, ISO 11137-2:2013 and 11137-3:2017.

➤ **Shelf Life**

Accelerated aging testing was performed to assure the shelf-life of 3 years in accordance with ASTM F1980-21.

➤ **Package Integrity Testing**

Pouch integrity (bubble test) was conducted according to ASTM F2096-11(2019).

➤ **Simulated Transportation Testing**

The simulated transportation testing was conducted according to ASTM D4169-23.

8. Clinical Testing

This 510(k) submission did not utilize clinical study for establishing substantial equivalence, therefore this section does not apply.

9. Conclusions

The comparison of the design specifications and results of non-clinical testing between the proposed device and the legally marketed predicate device (K192468) demonstrate that they are Substantially Equivalent (SE).