October 13, 2017

Zhanjiang Star Enterprise Co., Ltd
% Elly Xu
Consultant Manager
Shenzhen Joyantech Consulting Co., Ltd
Room 1122, No.55 Shizhou Middle Road, Nanshan District
Shenzhen, Guangdong GD755
CHINA

Re: K170233
Trade/Device Name: Disposable Urinary Catheter (PVC Urinary Catheter, Silicone Urinary Catheter, Latex Urinary Catheter)
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: EZD, EZL
Dated: August 5, 2017
Received: September 1, 2017

Dear Elly Xu:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Joyce M. Whang -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170233

Device Name
Disposable Urinary Catheter

Indications for Use *(Describe)*
The PVC Urinary Catheter is launched for clean intermittent catheterization (CIC) treatment. It is intended for use in the drainage of fluid from the urinary tract. It is indicated for use in male, female, and pediatric patients 2-12 years old.

The Silicone Urinary Catheter is intended to be placed in the bladder, through the urethra, to drain urine into a collection device. Two-way catheters are intended for urological bladder drainage only. Three-way catheters are intended for urological bladder drainage and bladder irrigation. It is indicated for use in male, female, and pediatric patients 2-12 years old.

The Latex Urinary Catheter is intended to be placed in the bladder, through the urethra, to drain urine into a collection device. Neleton catheters are launched for clean intermittent catheterization (CIC). Two-way catheters are intended for urological bladder drainage only. Three-way catheters are intended for urological bladder drainage and bladder irrigation. It is indicated for use in male, female, and pediatric patients 2-12 years old.

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)

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VOL 005_510(k) Summary

1. Submission Sponsor

Applicant Name	Zhanjiang Star Enterprise Co., Ltd
Address	NO.1, West Jinhua Rd. Zhanjiang, Guangdong, P. R. CHINA
Post Code	524094
Phone No.	86-759-2701619
Fax No.	86-759-2706838
Contact Person	Rongsheng Tang
Email	Tangrs@starcompany.com.cn
Date Prepared	2017-08-19

2. Submission correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
Address	Room 1122, No.55 Shizhou Middle Road, Nanshan District, Shenzhen, Guangdong, P.R.China
Post Code	518000
Phone No.	86-755-86069197
Contact Person	Elly Xu; Field Fu
Email	elly@cefda.com; cefda13485@163.com

3. Devices Identification

Trade name	Disposable Urinary Catheter
Common name	Disposable Urinary Catheter
Model	PVC Urinary Catheter, Silicone Urinary Catheter, Latex Catheter
Classification	II
Classification name	Urological catheter and accessories
Regulation number	876.5130
Product code	EZD, EZL
510(k) review panel	Gastroenterology/Urology
Performance standards	The performance and safety was evaluated in accordance with EN 1616:1997(R2007) and ASTM F623-99(2013). Biocompatibility tests were done in conformance with relevant requirements of ISO10993.

4. Legally Marketed Predicate Devices

Trade Name	Bard RiteCath Intermittent Urinary Catheter
Regulation number	876.5130
Regulation class	II
Regulation name	Urological catheter and accessories
510(k) Number	K142575
Product Code	EZD
Manufacturer	BARD Medical Division C. R. BARD, Inc.

Trade Name	Disposable Silicone Foley Catheter
Regulation number	876.5130
Regulation class	II
Regulation name	Urological catheter and accessories
510(k) Number	K130908
Product Code	EZL
Manufacturer	Guangdong Baihe Medical Technology Co., Ltd.

Trade Name	Medline Latex Foley Catheter
Regulation number	876.5130
Regulation class	II
Regulation name	Urological catheter and accessories
510(k) Number	K071423
Product Code	EZL
Manufacturer	Medline Industries, Inc.

5. Device Description

Disposable urinary catheter is a kind of disposable product which is used for draining the bladder, for temporary or short term. Based on the materials, the disposable urinary catheter includes PVC Urinary Catheter, Silicone Urinary Catheter and Latex Urinary Catheter.

PVC Urinary Catheter

PVC Urinary Catheter only has nelaton type structure, which is made of PVC and is intended for draining the bladder for short term. PVC Urinary Catheter consists of drainage funnel, drainage lumen, eyelets and tip. It is supplied in French size ranging from 8 to 20F. The catheters come in sizes from 12Fr-20Fr for adults and 8Fr-10Fr for pediatrics 2 -12 years old.

Silicone Urinary Catheter

Silicone Urinary Catheter is made of pure silicone. It is intended to be placed in the bladder, through the urethra, to drain urine into a collection device and has two-way type and three-way type. The two-way type consists of funnel, drainage lumen, drainage

eyes, balloon, inflating connector and valve. The three-way type consists of Funnel, Drainage lumen, Injection connector, injection lumen, drainage eyes, balloon, inflating connector and valve. Both of them are supplied in French size ranging from 8 to 24F. The catheters come in sizes from 12Fr-24Fr for adults and 8Fr-10Fr for pediatrics 2 -12 years old.

Latex Urinary Catheter

Latex Foley Catheter is made of nature latex, which has nelaton type, two-way type and three-type.

The nelaton Latex Urinary Catheter is intended for draining the bladder for short term and consists of drainage funnel, drainage lumen, eyelets and tip. The nelaton catheters come in sizes from 12Fr-20Fr for adults and 8Fr-10Fr for pediatrics 2-12 years old.

The two-way type and three-way type are intended to be placed in the bladder, through the urethra, to drain urine into a collection device. The two-way type consists of funnel, drainage lumen, drainage eyes, balloon, inflating connector and valve. The three-way type consists of Funnel, Drainage lumen, Injection connector, injection lumen, drainage eye. Both of them are supplied in French size ranging from 8 to 24F. The catheters come in sizes from 12Fr-24Fr for adults and 8Fr-10Fr for pediatrics 2 -12 years old.

6. Indications for Use Statement

- The PVC Urinary Catheter is launched for clean intermittent catheterization (CIC) treatment. It is intended for use in the drainage of fluid from the urinary tract. It is indicated for use in male, female, and pediatric patients 2-12 years old.
- The Silicone Urinary Catheter is intended to be placed in the bladder, through the urethra, to drain urine into a collection device. Two-way catheters are intended for urological bladder drainage only. Three-way catheters are intended for urological bladder drainage and bladder irrigation. It is indicated for use in male, female, and pediatric patients 2-12 years old.
- The Latex Urinary Catheter is intended to be placed in the bladder, through the urethra, to drain urine into a collection device. Neleton catheters are launched for clean intermittent catheterization (CIC). Two-way catheters are intended for urological bladder drainage only. Three-way catheters are intended for urological bladder drainage and bladder irrigation. It is indicated for use in male, female, and pediatric patients 2-12 years old.

7. Substantial Equivalence Discussion

7.1 Comparison between PVC Urinary Catheter and Bard RiteCath Intermittent Urinary Catheter

Item	Proposed Device: PVC Urinary Catheter	Predicate Device: Bard RiteCath Intermittent Urinary Catheter (K142575)	Comments
Product Code	EZD	EZD	Same
Intended Use	The PVC Urinary Catheter is launched for clean intermittent catheterization (CIC) treatment. It is intended for use in the drainage of fluid from the urinary tract. It is indicated for use in male, female, and pediatric patients 2-12 years old.	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
Device Structure	Color-coded funnel, shaft, eyelets and tip	Color-coded funnel, shaft, staggered eyelets and tip	Same
Catheter material	PVC	PVC	Same
Size	Male: 12Fr-20Fr	Male: 12Fr-18Fr	Similar. Compared with the predicate device, the proposed device has 20Fr. The 20Fr size for Urinary Catheter is widely used in the market and had been approved in FDA (Such as K142563, K130908). And the sizes for pediatric is covered in the scope of predicate device.
	Female: 12Fr-20Fr	Female: 12Fr-18Fr	
	Pediatric: 8Fr-10Fr	Pediatric: 6Fr-10Fr	
Condition of use	It is used for clean intermittent catheterization (CIC) treatment.	It is used for clean intermittent catheterization (CIC) treatment.	Same
Sterilization	SAL: 10^{-6}	SAL: 10^{-6}	Same
	Method: EO Sterilized	Method: EO Sterilized	Same
Performance	Complied with BS EN 1616: 1997(R2007)	Complied with BS EN 1616: 1997(R2007)	Same
Shelf Life	4 years	Unknown	The shelf life of 4 years has been verified and the test report is shown in VOL_14.

Item		Proposed Device: PVC Urinary Catheter	Predicate Device: Bard RiteCath Intermittent Urinary Catheter (K142575)	Comments
Single Use		Yes	Yes	Same
Biocompatibility	Cytotoxicity	ISO 10993-5:2009	ISO 10993-5:2009	Same
	Sensitization, irritation	ISO 10993-10:2010	ISO 10993-10:2010	Same
	Systemic toxicity	ISO 10993-11:2006	ISO 10993-11:2006	Same
	Implantation	ISO 10993-6:2007	ISO 10993-6:2007	Same

7.2 Comparison between Silicone Urinary Catheter and Bard RiteCath Intermittent Urinary Catheter

Item	Proposed Device: Silicone Urinary Catheter	Predicate Device: Disposable Silicone Foley Catheter (K130908)	Comments
Product Code	EZL	EZL	Same
Intended Use/Indications for Use	The Silicone Urinary Catheter is intended to be placed in the bladder, through the urethra, to drain urine into a collection device. Two-way catheters are intended for urological bladder drainage only. Three-way catheters are intended for urological bladder drainage and bladder irrigation. It is indicated for use in male, female, and pediatric patients 2-12 years old.	Two-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage for urological use only; the indwell time of the proposed device 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 indwell time of the proposed device is no more than 30 days.	Same

Item		Proposed Device: Silicone Urinary Catheter	Predicate Device: Disposable Silicone Foley Catheter (K130908)	Comments
Device Structure		Two-way: double lumen tube, a double lumen hub, a balloon and a tip	Two-way: double lumen tube, a double lumen hub, a balloon and a tip	Same
		Three- way: a triple lumen tube, a triple lumen hub, a balloon and a tip	Three- way: a triple lumen tube, a triple lumen hub, a balloon and a tip	Same
Catheter material		silicone	silicone	Same
Size		Male: 12Fr-24Fr	Male: 12-26Fr	Similar. Similar. The size of proposed device is included in the scope of the predicate device.
		Female: 12Fr-24Fr	Female:12-26Fr	
		Pediatric: 8Fr,10Fr	Pediatric: 6Fr,8Fr, 10Fr	
Balloon size		3 mL, 5 mL, 15 mL, 30 mL	1.5 mL, 3 mL, 5 mL, 10 mL, 15 mL, 20 mL, 30 mL	Similar. The balloon size of proposed device is included in the scope of the predicate device.
Condition of use		Indwelling catheterization treatment.	Indwelling catheterization treatment.	Same
Sterilization		SAL: 10^{-6}	SAL: 10^{-6}	Same
		Method: EO Sterilized	Method: EO Sterilized	Same
Performance		Complied with ASTM F623-99(2013)	Complied with ASTM F623-99(2013)	Same
Shelf Life		4 years	Unknown	The shelf life of 4 years has been verified and the test report is shown in VOL_14.
Single Use		Yes	Yes	Same
Biocompatibility	Cytotoxicity	ISO 10993-5:2009	ISO 10993-5:2009	Same
	Sensitization,	ISO 10993-10:2010	ISO 10993-10:2010	Same

Item		Proposed Device: Silicone Urinary Catheter	Predicate Device: Disposable Silicone Foley Catheter (K130908)	Comments
	irritation			
	Systemic toxicity	ISO 10993-11:2006	ISO 10993-11:2006	Same
	Implantation	ISO 10993-6:2007	ISO 10993-6:2007	Same

7.3 Comparison between Latex Urinary Catheter and Bard RiteCath Intermittent Urinary Catheter

Item	Proposed Device: Latex Urinary Catheter	Predicate Device: Medline Latex Foley Catheter (K071423)	Comments
Product Code	EZL	EZL	Same
Intended Use/Indications for Use	The Latex Urinary Catheter is intended to be placed in the bladder, through the urethra, to drain urine into a collection device. Neleton catheters are launched for clean intermittent catheterization (CIC). Two-way catheters are intended for urological bladder drainage only. Three-way catheters are intended for urological bladder drainage and bladder irrigation. It is indicated for use in male, female, and pediatric patients 2-12 years old.	The Medline Latex Foley Catheter is intended to be used as a urological catheter inserted through the Urethral for the purpose of draining urine and other fluids from the urinary tract.	Similar. See Issue 1.
Device Structure	Neleton: funnel, shaft, eyelets and tip	/	Different. See Issue 1.

Item	Proposed Device: Latex Urinary Catheter	Predicate Device: Medline Latex Foley Catheter (K071423)	Comments
	Two-way: double lumen tube, a double lumen hub, a balloon and a tip	Two-way: double lumen tube, a double lumen hub, a balloon and a tip	Same
	Three- way: a triple lumen tube, a triple lumen hub, a balloon and a tip	Three- way: a triple lumen tube, a triple lumen hub, a balloon and a tip	Same
Catheter material	Natural rubber latex, Silicone coating	Natural rubber latex, Silicone coating	Same
Size	Male: 12Fr-24Fr	Male: 12-30Fr	Similar. The size of proposed device is included in the scope of the predicate device.
	Female: 12Fr-24Fr	Female:12-30Fr	
	Pediatric: 8Fr,10Fr	Pediatric: 6Fr,8Fr, 10Fr	
Balloon size	3 mL, 5 mL, 15 mL, 30 mL	3 mL, 5 mL, 30 mL	Similar. Both of the proposed device and predicate device have the same scope of balloon size. And the proposed device has more optional sizes.
Condition of use	Neleton: CIC treatment	/	Different. See Issue 1
	Two-way and three-way: Indwelling catheterization treatment.	Indwelling catheterization treatment	Same
Sterilization	SAL: 10^{-6}	SAL: 10^{-6}	Same

Item		Proposed Device: Latex Urinary Catheter	Predicate Device: Medline Latex Foley Catheter (K071423)	Comments
		Method: EO Sterilized	Method: Gamma Irradiation	Different. See Issue 2.
Performance		Complied with BS EN 1616: 1997(R2007) and ASTM F623-99(2013)	Complied with ASTM F623-99(2013)	Same
Shelf Life		4 years	Unknown	The shelf life of 4 years has been verified and the test report is shown in VOL_14.
Single Use		Yes	Yes	Same
Biocompatibility	Cytotoxicity	ISO 10993-5:2009	ISO 10993-5:2009	Same
	Sensitization, irritation	ISO 10993-10:2010	ISO 10993-10:2010	Same
	Systemic toxicity	ISO 10993-11:2006	ISO 10993-11:2006	Same
	Implantation	ISO 10993-6:2007	ISO 10993-6:2007	Same

Issue 1: The proposed device has the Neleton type structure compared with the predicate device. As the neleton type has less dwell time compared with the Foley Catheter (two-way and three-way Urinary Catheter), it has less likely to cause a urinary-tract infection in these situations. Moreover, the biocompatibility test reports and the bench test reports for neleton type of the proposed device demonstrate that proposed device is biocompatible and the performance as intended.

Issue 2: Although the sterilization methods between the proposed device and the predicate device are different, but the EO sterilization effect of the proposed device is proved by the *Sterilization validation report in* VOL_014. The validation report showed that the sterilization effect of the proposed device can achieve a Sterility Assurance Level (SAL) of 10^{-6}.

8. Non-clinical Testing

All nonclinical testing performed on new devices is to demonstrate the substantial

equivalence to the predicate devices. Tests setup and execution are performed in accordance with applicable standards. Results of the testing are demonstrating the compliance to the standards and matching the performance of new devices to the predicate devices.

The following performance data were provided in support of the substantial equivalence determination.

8.1 PVC Urinary Catheter

Test		Requirements	Results
Surface finish		Meet the requirement of 4.2 of EN 1616: 1997(R2007).	Passed
Dimensions		Meet the requirement of 4.3 of EN 1616: 1997(R2007).	Passed
Strength		Meet the requirement of 4.4 of EN 1616: 1997(R2007).	Passed
Connector security		Meet the requirement of 4.5 of EN 1616: 1997(R2007).	Passed
Flow rates		Meet the requirement of 4.8 of EN 1616: 1997(R2007).	Passed
Biocompatibility	Cytotoxicity	ISO 10093-5 Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity	Passed
	Sensitization	ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization	Passed
	Irritation	ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization	Passed
	Systemic toxicity	Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity	Passed
Sterility		SAL≤ 10^{-6}.	Passed

8.2 Silicone Urinary Catheter

Test	Requirements	Results
Flow rate through drainage lumen	Meet the requirement of 4.1 of ASTM F623-99(2013)	Passed
Balloon Integrity	Meet the requirement of 4.2 of ASTM F623-99(2013)	Passed
Inflated Balloon Response to Traction	Meet the requirement of 4.3 of ASTM F623-99(2013)	Passed
Balloon Volume Maintenance	Meet the requirement of 4.4 of ASTM F623-99(2013)	Passed
Balloon Size and Shaft Size	Meet the requirement of 4.5 of ASTM F623-99(2013)	Passed

Deflation Reliability (Failure to Deflate)		Meet the requirement of 4.6 of ASTM F623-99(2013)	Passed
Biocompatibility	Cytotoxicity	ISO 10093-5 Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity	Passed
	Sensitization	ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization	Passed
	Irritation	ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization	Passed
	Systemic toxicity	Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity	Passed
	Implantation	Biological Evaluation Of Medical Devices - Part 6: Tests For Local Effects After Implantation	Passed
Sterility		SAL shall be less than 10^{-6}.	Passed

8.3 Latex Urinary Catheter

Test		Requirements	Results
Surface finish		Meet the requirement of 4.2 of EN 1616: 1997(R2007).	Passed
Dimensions		Meet the requirement of 4.3 of EN 1616: 1997(R2007).	Passed
Strength		Meet the requirement of 4.4 of EN 1616: 1997(R2007).	Passed
Connector security		Meet the requirement of 4.5 of EN 1616: 1997(R2007).	Passed
Flow rates		Meet the requirement of 4.8 of EN 1616: 1997(R2007) and 4.1 of ASTM F623-99(2013).	Passed
Balloon Integrity		Meet the requirement of 4.2 of ASTM F623-99(2013)	Passed
Inflated Balloon Response to Traction		Meet the requirement of 4.3 of ASTM F623-99(2013)	Passed
Balloon Volume Maintenance		Meet the requirement of 4.4 of ASTM F623-99(2013)	Passed
Balloon Size and Shaft Size		Meet the requirement of 4.5 of ASTM F623-99(2013)	Passed
Deflation Reliability (Failure to Deflate)		Meet the requirement of 4.6 of ASTM F623-99(2013)	Passed
Biocompatibility	Cytotoxicity	ISO 10093-5 Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity	Passed
	Sensitization	ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin	Passed

		sensitization	
	Irritation	ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization	Passed
	Systemic toxicity	Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity	Passed
	Implantation	Biological Evaluation Of Medical Devices - Part 6: Tests For Local Effects After Implantation	Passed
Sterility		SAL≤ 10^{-6}.	Passed

9. Clinical Testing

Substantial equivalence does not depend on clinical test data.

10. Conclusions

Based on device comparison information and non-clinical bench testing, the proposed device is substantially equivalent to legally marketed predicate devices.