DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 3, 2016

Shaoxing Fuqing Health Products Co., Ltd.
% Mike Gu
RA Manager
Osmunda Medical Device Technology Service Co., Ltd
Floor 7, Jingui Business Building
982 Congyun Rd., Baiyum District
Guangzhou 510420
China

Re: K151745
Trade/Device Name: FULL CARE Disposable PVC Nelaton Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: EZD
Dated: January 28, 2016
Received: February 2, 2016

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.

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 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 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 yours,

Herbert P. Lerner -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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K151745

Device Name
FULL CARE Disposable PVC Nelaton Catheter

Indications for Use *(Describe)*
The FULL CARE Disposable PVC Nelaton 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. The urinary catheter comes in a variety of sizes packaged sterile for single-use.

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.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

I. SUBMITTER

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Shaoxing Fuqing Health Products Co., Ltd.

Date Prepared: April 14, 2015

II. DEVICE

Name of Device: FULL CARE Disposable PVC Nelaton Catheter

Common/Usual Name: Urethral Catheter

Classification Names: Catheter, Urethral (21 CFR876.5130)

Regulation Class: II

Product Code: GBM, EZD, FCM

III. PREDICATE DEVICE

Cure Catheter™, K072539

Cure Pediatric Catheter, K110653

Cure Catheter™ Hydrophilic Coated, K132500

Cure Catheter™ Closed System, K080881

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

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The FULL CARE Disposable PVC Nelaton Catheter is a sterile, single use device designed as an intermittent pathway for drainage of the bladder. It is available for male, female and pediatric, in uncoated and coated variants and in two different tip configurations (straight and rounded). There are two drainage eyelets on the catheter.

The PVC catheter is designed as an intermittent pathway for drainage of the bladder. The devices consist of the following parts(with different combination):

- Intermittent Urinary Catheter;
- hydrophilic coated Nelaton Catheter;
- water sachet;
- collection bag;
- gauze tissue;
- povidone iodine swabs ;
- two gloves;
- underpad;
- BZK;
- Lubricant;
- Interface tube;
- pouch

The device is made of polyvinyl chloride. The catheter is provided sterile in a variety of lengths and sizes.

V. INDICATIONS FOR USE

The FULL CARE Disposable PVC Nelaton 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. The urinary catheter comes in a variety of sizes packaged sterile for single-use.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The sponsor identified the similarities and differences of the proposed FULL CARE Disposable PVC Nelaton Catheter device to the legally marketed predicates K072539, K110653, K132500 and K080881 to which substantial equivalency is claimed.

Specification	Predicate Device	Predicate Device	Proposed
Device name	Cure Catheter™	Cure Pediatric Catheter	Nelaton Catheter (NC)
510k number	K072539	K110653	NA
Manufacturer	Cure Medical, LLC	Cure Medical, LLC	Shaoxing Fuqing Health Products Co., Ltd

Indications for Use	The FULL CARE Disposable PVC Nelaton 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. The urinary catheter comes in a variety of sizes packaged sterile for single-use.	An intermittent urinary catheter that is inserted through the urethra and indicated for the purpose of bladder drainage for pediatric males and females. The urinary catheter comes in a variety of sizes packaged sterile for single-use.	The FULL CARE Disposable PVC Nelaton 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. The urinary catheter comes in a variety of sizes packaged sterile for single-use.
Patient Population	Available for male and female	Available for pediatric male and female	Available for male and female, and pediatric male and female.

Dimension	Female straight tip 6 inch from 8Fr to 18Fr with 2Fr increments; Male straight tip 16 inch from 8Fr to 18Fr with 2Fr increments.	Pediatric straight tip 10 inch from 8Fr to 14Fr with 2Fr increments;	Male NC without lubricant is available from 8Fr to 20Fr, female NC without lubricant is available from 8Fr to 16Fr with 2Fr increments; Both male and female NC with lubricant is available from 8Fr to 18Fr with 2Fr increments; Pediatric is available from 6Fr to 10Fr with 2Fr increments.
Sterilization method	EO	EO	EO
Material	PVC	PVC	PVC

Specification	Predicate Device	Proposed
Device name	Cure Catheter™ Hydrophilic Coated	Hydrophilic Coated Nelaton Catheter (HNC)
510k number	K132500	NA
Manufacturer	Cure Medical, LLC	Shaoxing Fuqing Health Products Co., Ltd

Indications for Use	The Cure Catheter™ Hydrophilic Coated is an intermittent urinary catheter that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females. The urinary catheter comes in a variety of sizes packaged sterile for single-use.	The FULL CARE Disposable PVC Nelaton 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. The urinary catheter comes in a variety of sizes packaged sterile for single-use.
Patient Population	Available for male and female	Available for male and female
Dimension	Female 6 inch straight tip in size from 6Fr to 18Fr with 2Fr increments; Male 16 inch straight and coude tip in size from 8Fr to 18Fr with 2Fr increments; Pediatric 10 inch straight tip in size from 6Fr to 14Fr with 2Fr increments;	The CB is available in size from 8Fr to 16Fr with 2Fr increments; The Smile Cath is available in size from 8Fr to 18Fr with 2Fr increments; The CS1 and CS2 are available in size from 8Fr to 16Fr with 2Fr increments;
Sterilization method	EO for catheter and Radiation for water sachet	EO for catheter and Radiation for water sachet
Material	PVC catheter with DSM Comfort Coat-polyvinylpyrrolidone-Hydrophilic Material Coating-and sterile water sachet	PVC catheter with P41001 coat, and purified water.

Specification	Predicate Device	Proposed
Device name	Cure Catheter® Closed Systems	Intermittent Catheterization Bag (CB)+ Intermittent Catheterization Kit (Smile- Cath)+ Intermittent Catheterization Kit (CS1)+ Intermittent Catheterization Kit (CS2)
510k number	K080881	NA

Manufacturer	Cure Medical, LLC	Shaoxing Fuqing Health Products Co., Ltd
Indications for Use	The Cure Catheter Closed System is an intermittent urinary catheter attached to a collection bag that is inserted through the urethra and indicated for the purpose of bladder drainage for males and females. The urinary catheter comes in a variety of sizes packaged sterile for single-use.	The FULL CARE Disposable PVC Nelaton 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. The urinary catheter comes in a variety of sizes packaged sterile for single-use.
Patient Population	Available for male and female	Available for male and female
Dimension	The CB is available in size from 8Fr to 16Fr with 2Fr increments; The CS is available in size from 8Fr to 16Fr with 2Fr increments;	The CB is available in size from 8Fr to 16Fr with 2Fr increments; The Smile Cath is available in size from 8Fr to 18Fr with 2Fr increments; The CS1 and CS2 are available in size from 8Fr to 16Fr with 2Fr increments;
Anatomical Sites	Urethra, bladder	Urethra, bladder
Sterilization method	EO	EO
Material	PVC	PVC
Kit	Cure Catheter, collection bag, a BZK wipe, three Povidone-iodine swabsticks, one pair of gloves, a sterile wipe, and an underpad	CS1:CB, underpad, gauze tissue, povidone iodine swab, a BZK wipe, one pair of gloves. CS2: NC, collection bag, a BZK wipe, underpad, one pair of gloves, lubricant,

VII. PERFORMANCE DATA

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

Biocompatibility testing:

The biocompatibility evaluation for the Disposable PVC Nelaton Catheter was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The catheter testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The catheter is considered surface contacting for duration of less than 24 hours.

Bench testing:

- EN 1616:1997+A1:1999
- EN 1618:1997

It's found from the test results that the proposed devices meet the requirements.

Animal and clinical study:

The subject of this premarket submission, Disposable PVC Nelaton Catheter, does not require clinical studies to support substantial equivalence.

VIII. CONCLUSIONS

Shaoxing Fuqing Health Products Co., Ltd. considers the Disposable PVC Nelaton Catheter does not raise any new issues of safety or effectiveness. And is substantially equivalent to the predicate devices.