January 24, 2018

Fresenius Medical Care Renal Therapies Group, LLC
Denise Oppermann
Senior Director, Regulatory Affairs
920 Winter Street
Waltham, MA 02451

Re: K173363
Trade/Device Name: Cycler Drain Bag Set
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal Dialysis System and Accessories
Regulatory Class: II
Product Code: KDJ
Dated: October 25, 2017
Received: October 26, 2017

Dear Denise Oppermann:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

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)*
K173363

Device Name
Cycler Drain Bag Set

Indications for Use *(Describe)*
The Cycler Drain Bag Set is indicated for use by patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD) in a healthcare facility or at home. The Cycler Drain Bag Set is an optional receptacle that connects to the Luer-lock end of a Cycler Set drain line in order to collect patient effluent during PD treatments. This device is to be used only with Fresenius Medical Care (FMCNA) Cyclers and Cycler Sets.

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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5. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR §807.92.

5.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 699-4479
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann Senior Director Regulatory Affairs – Devices
Preparation Date:	October 27, 2017

5.2. Device Name

Trade Name:	Cycler Drain Bag Set
Common Name:	Drain Bag Set
Classification Name:	Peritoneal Dialysis System and Accessories
Regulatory Class:	Class II per 21 CFR §876.5630
Product Code:	KDJ
Classification Panel:	Gastroenterology/Urology

5.3. Legally Marketed Predicate Device

The legally marketed predicate device is the Peritoneal Dialysis Drainage Set (K895991). This predicate has not been subject to a design-related recall.

5.4. Device Description

5.4.1. Device Identification

The Cycler Drain Bag Set (hereinafter referred to as "Drain Bag Set") is the subject of this 510(k).

5.4.2. Device Characteristics

The Drain Bag Set is a new, single-use device designed to collect patient effluent during the drain phase of an Automated Peritoneal Dialysis (APD) treatment. The Drain Bag Set is provided sterile and non-pyrogenic. The Drain Bag Set is sterilized using ethylene oxide (EO).

5.4.3. Environment of Use

The Drain Bag Set is used in both healthcare and home environments.

5.4.4. Brief Written Description of the Device

The Drain Bag Set (tubings and flexible bags) is a passive, closed drainage system used as an optional receptacle during an APD treatment. The Drain Bag Set is used to collect effluent in bags rather than letting the effluent flow directly to a drain. The Drain Bag Set connects to the drain line of a cycler set to collect patient effluent by means of gravity and the pumping action of a Peritoneal Dialysis (PD) cycler. The Drain Bag Set connects to the drain line using a standard Luer lock connection. The Drain Bag Set consists of three (3) interconnected 7-liter drain bags, each with a sampling port and an occluding clamp. The tubing lines that connect each drain bag to the drain line have a snap-disconnect tubing segment. This tubing segment allows the user to disconnect individual bags by snapping the tubing apart.

5.4.5. Materials of Use

The component materials of the Drain Bag Set do not come into direct or indirect contact with the patient's body tissue and are classified as "non-contact" in accordance with FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* (16 June 2016).

The Drain Bag Set components are composed of the following materials:

Drain Bag Set Components	**Material**
Drain bag Tubing Male Luer lock adapter Vented cap for adapter	Polyvinyl Chloride (PVC)
Clamp Triple "Y" connector	Polypropylene (PP)
Snap-disconnect tubing segment	Polycarbonate (PC)
Sampling port	PC, Siliprene

5.4.6. Key Performance Characteristics

The Drain Bag Set is designed to be compatible with the Luer lock end of the Cycler Set drain line of Fresenius PD Cycler Sets. The drain bags have sampling ports that enable effluent sampling as needed. Each drain bag has a 7-liter nominal capacity and 8-liter maximum capacity.

5.5. Intended Use

The Drain Bag Set is intended for use by patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis in a healthcare facility or at home. It is designed for use as an optional receptacle to collect patient effluent during an APD treatment with Fresenius PD Cyclers and Fresenius PD Cycler Sets.

5.6. Indications for Use

The Cycler Drain Bag Set is indicated for use by patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD) in a healthcare facility or at home. The Cycler Drain Bag Set is an optional receptacle that connects to the Luer-lock end of a Cycler Set drain line in order to collect patient effluent during PD treatments. This device is to be used only with Fresenius Medical Care (FMCNA) Cyclers and Cycler Sets.

5.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the Drain Bag Set are equivalent to the predicate Peritoneal Dialysis Drainage Set (K895991).

- Similar principle of operation
- Similar design characteristics
- Same sterilization method
- Same intended use

5.8. Performance Data

A summary of testing conducted to support the determination of substantial equivalence is as follows:

Test Conducted	**Test Method Description**	**Acceptance Criteria**	**Results/ Conclusion**
Drop Test	The drain bag was filled to capacity with water and dropped from a height of 0.25 m. The test was performed in accordance with ISO 15747:2010 *Plastic Containers for Intravenous Injections.*	The drain bag shall not leak (visual inspection). Acceptance criteria from ISO 15747:2010 were applied.	Pass, results within acceptance criteria

Test Conducted	**Test Method Description**	**Acceptance Criteria**	**Results/ Conclusion**
Internal Pressure Test	The drain bags were exposed to an internal pressure of 50 kPa between two plane parallel plates maintaining the pressure for 15 minutes. The test was performed in accordance with ISO 15747:2010 *Plastic Containers for Intravenous Injections.*	The drain bag shall not leak (visual inspection) Acceptance criteria from ISO 15747:2010 were applied.	Pass, results within acceptance criteria
Hanger Holes Tensile Strength	The drain bags were filled to capacity with water and were hung on a medical hooking pole by attaching a load of 3.5 lbs (15 N) for 60 minutes. The test was performed in accordance with ISO 15747:2010 *Plastic Containers for Intravenous Injections.*	The drain bag hanger holes shall withstand a tensile load of 15 N for 60 minutes. Acceptance criteria from ISO 15747:2010 were applied.	Pass, results within acceptance criteria
Film Roughness Test	The drain bag film roughness was measured in three different locations – bottom, middle, and top of the bag– with a roughness meter.	The drain bag's film shall have a roughness ≤ 0.75 µm (Roughness Average)	Pass, results within acceptance criteria
Tensile Strength of Bonding Engagements	A pull-off test was performed using the applicable fixture for each bonded engagement with the Instron machine.	All bonded engagements between plastic composites shall require >10 lbf to detach.	Pass, results within acceptance criteria
Maintenance of Sterility testing	The vented cap was validated as a sterile barrier via the dust drum microbial challenge test per ANSI/AAMI/ISO 11607-1:2006/(R) 2010 - A1:2014 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging.*	Acceptance criteria from ISO 11607-1:2006/(R) 2010 - A1:2014 were applied.	Pass, results within acceptance criteria
Male Luer lock connector testing	The eight (8) Male Luer lock connector tests were performed in accordance with ISO 594-2:1998 *Conical Fittings with 6% (Luer) Taper for Syringes, Needles and certain other Medical Equipment. Part 2: Local Fittings* standard.	Acceptance criteria from ISO 594-2:1998 were applied.	Pass, results within acceptance criteria

Test Conducted	**Test Method Description**	**Acceptance Criteria**	**Results/ Conclusion**
Drain Bag Set Capacity	The drain bags were filled to capacity with water and it was observed if they were able to contain such volume.	The Drain Bag Set shall hold at least 24 L of water (volume ≥ 24 L)	Pass, results within acceptance criteria
Sampling Port (i.e., injection site) Leakage Test	The sampling port was punctured using a 23 gauge needle for 15 seconds and was then exposed to an internal air pressure of 20 kPa. The samples were submerged in water for 15 seconds and air leakages were inspected. The test was performed in accordance with ISO 15747:2010 *Plastic Containers for Intravenous Injections.*	The sampling port shall not leak after being punctured with a 23 gauge needle one time for 15 seconds and subjected to a pressure of 20 kPa under water for 15 seconds. Acceptance criteria from ISO 15747:2010 were applied.	Pass, results within acceptance criteria
Snap Connector Breakage Test	The snap connector was placed in a poka-yoke mechanism and subjected to a compression test with the Instron machine starting from the injection point (0°) and testing at 90°, 180°, and 270°.	The snap connector shall have a break point between 60 oz-in and 120 oz-in	Pass, results within acceptance criteria
Clamp Test	After activating the clamp on the tubing, the tubing was submerged and pressurized to 15 psi for 10 minutes. Any leaks past the clamp were observed. This test method was adopted from ISO 8638:2010 Section 5.5.1.1 *Cardiovascular implants and extracorporeal systems — Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters*	No leaks past the clamp. Acceptance criteria from ISO 8638:2010 were applied.	Pass, results within acceptance criteria

Test Conducted	Test Method Description	Acceptance Criteria	Results/ Conclusion
Vibratory (ship) Testing	A simulated shipping distribution test was performed using rotary motion. The package was exposed to repetitive shocks for a period of 60 minutes with a frequency of 270 cycles per minute. The test was performed in accordance with ASTM D4169-14 *Standard Practice for Performance Testing of Shipping Containers and Systems*	No tubing kinks or loose or damaged components	Pass, results within acceptance criteria

Results of the design verification tests met the design requirements for the proposed device and demonstrated that, like the predicate device, it is safe and effective for its intended use.

5.8.1. Biocompatibility Testing

No biocompatibility tests were performed.

5.8.2. Human Factors Validation Testing

The Drain Bag Set was validated for its safe and effective use in accordance with FDA guidance *Applying Human Factors and Usability Engineering to Medical Devices* (03 February 2016).

5.8.3. Software Verification and Validation Testing

Not applicable. The Drain Bag Set does not contain software.

5.8.4. Mechanical and Acoustic Testing

No mechanical or acoustic tests were performed.

5.8.5. Animal Studies

No animal studies were performed.

5.8.6. Clinical Studies

No clinical studies were performed.

5.9. Conclusion

The intended use, design, principle of operation, and sterilization method of the Drain Bag Set is the same as that of the predicate device. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the Drain Bag Set device is safe and effective for its intended use.