March 18, 2022

Baxter Healthcare Corporation
c/o Maninee Patel
Associate Director, Regulatory Affairs
One Baxter Parkway
Deerfield, Illinois 60015

Re: Trade/Device Name: 15L Cycler Drainage Bag
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal Dialysis System And Accessories
Regulatory Class: II
Product Code: KDJ
Received: December 22, 2021

Dear Maninee Patel:

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,

for
Gema Gonzalez
Acting Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

ADDITIONAL CONSIDERATIONS

The following are FDA suggestions, recommendations, or requests that did not preclude a favorable decision on the marketing application. A complete response to additional considerations is not required.

Sterility

In Appendix 14-2, you provided a test report for accelerated aging of packaging using the sterile version of your Drainage Bag. However, in this test report you have stated that the Q10 was equal to 3. Per ASTM F1980-16, "Using the Arrhenius equation with Q10 equal to 2 is a common and conservative means of calculating an aging factor. NOTE 6—A more aggressive reaction rate coefficient, for example, Q10 = 2.2 to 2.5, may be used if the system under investigation is sufficiently well characterized in the literature. The level and nature of damage must be similar to that reported in the literature to ensure that the reaction rate coefficient and accelerated aging temperature are maintained within appropriate boundaries. This is the responsibility of the manufacturer." Therefore, it is recommended that the Q10 equal 2 for accelerated aging to support packaging. In future submissions, please conduct accelerated aging using a Q10 equal to 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214016

Device Name
15L Cycler Drainage Bag

Indications for Use *(Describe)*
This bag is intended for the collection of effluent during Automated Peritoneal Dialysis (APD) Therapy.

Type of Use *(Select one or both, as applicable)*

[x] 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

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510(k) Summary

September 30, 2021

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

CONTACT PERSON:

Maninee Patel, PharmD
Associate Director, Global Regulatory Affairs
32650 N Wilson Road
Round Lake, IL 60073
Telephone: (224)217-7875

IDENTIFICATION OF THE DEVICE:

Common Name: Peritoneal dialysis system and accessories
Trade/Device Name: 15L Cycler Drainage Bag
Classification Panel: Gastroenterology/Urology
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal Dialysis Tubing Kit
Product Code: KDJ

Table 1. Current and Proposed Device Configuration

Product Code	Description
5C4145P *(currently marketed)*	15L Cycler Drainage Bag *(sterile)*
5C4145NS *(proposed)*	15L Cycler Drainage Bag *(non-sterile)*

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PREDICATE DEVICE:

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date	Product Codes
Cycler Drainage Set 15L Cycler Drainage Bag *(currently marketed)*	Baxter Healthcare Corporation (Submitted by Travenol Laboratories)	K791899	November 13, 1979	5C4145 5C4145P *(currently marketed)*

DESCRIPTION OF THE DEVICE:

Baxter's Cycler Drainage Bag product line currently consists of a sterile 15L Cycler Drainage Bag (5C4145P). This 15 L Cycler Drainage Bag is a single use device intended for the collection of effluent during Automated Peritoneal Dialysis (APD) Therapy and can be used with Baxter's APD Sets with Cassette, Manifold Sets and Extension Sets. The purpose of this drain bag is to allow the collection of the spent effluent in the event that a patient does not have access to a drain from the location where APD therapy is performed. This product line has been previously cleared under 510(k) premarket notification K791899 (cleared on November 13, 1979).

The basis for this submission is the addition of a non-sterile version of the 15L Cycler Drainage Bag to the current product line. The product line does not come into direct or indirect contact with the patient's body tissue. The intended use, material, design, and function of the proposed device will be the same as the currently marketed 15 L Cycler Drainage Bag.

INDICATIONS FOR USE:

This bag is intended for the collection of effluent during APD Therapy.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

In Table 3, the proposed device (5C4145NS) is compared to the currently marketed version of the predicate device (5C4145P).

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Table 3. Device Comparison

Features		Predicate Device 15L Cycler Drainage Bag (Product Code: 5C4145P – *currently marketed*)	Proposed Device 15L Cycler Drainage Bag (Product Code: 5C4145NS)	Assessment of Differences
Indications for Use		This bag is intended for the collection of effluent during APD Therapy.	Same	Not Applicable
Sterile and Non-Pyrogenic		Yes	No	Sterilization of the drain bag is not required for the patient to perform therapy and collect effluent safely. Testing demonstrates that control of product bioburden, the length of the drain line, and the flow rate of spent dialysate adequately mitigate the risk of contamination of the patient peritoneum from pathogens originating in the drain bag. Instructions for Use were updated accordingly to ensure no increased risk for patient.
Pump Compatibility and Electromechanical Device Compatibility		Homechoice, Homechoice Claria, and Amia	Same	Not Applicable
Single Use		Yes	Same	Not Applicable
Materials				
	Drain Bag Inlet and Outlet Tubing	Polyvinyl Chloride (PVC)	Same	Not Applicable
	Outlet Clamp	Polypropylene (PP)		
	Inlet Clamp	High Density Polyethylene (HDPE)		
	Drain Line Adapter	Acrylonitrile Butadiene Styrene (ABS)		
	Spike Connector	ABS		
	Pull Ring Cap	Low Density Polyethylene (LDPE)	Same	Not Applicable
	Tip Protector	LDPE		

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Table 3. Device Comparison

Features		Predicate Device 15L Cycler Drainage Bag (Product Code: 5C4145P – *currently marketed*)	Proposed Device 15L Cycler Drainage Bag (Product Code: 5C4145NS)	Assessment of Differences
	Flow Wrap Pouch	HDPE Film		
	Carton	Corrugated Cardboard		

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses to determine the design verification tests that need to be conducted based on the proposed change. All results meet the acceptance criteria, and support that the devices presented in this premarket notification are appropriately designed for their intended use.

Performance Data:

Table 4. Peformance Data

Test	Product Code Tested	Requirements
Capacity/Leak	5C4145P	The product shall hold 16 liters of water for 24 hours without leak.
	5C4145NS	The product shall hold 16 liters of water for 48 hours without leak.
Drain Line Spike/Leak	5C4145P, 5C4145NS	Force to spike drain line connector shall be no more than 35 lbf with no leak at 8psig for 10 seconds.
Drain Line Spike Removal	5C4145P	Force to remove spike connector after a 24-hour therapy shall be no less than 3 lbf.
	5C4145NS	Force to remove spike connector after a 48-hour therapy shall be no less than 3 lbf.
Clamp Closure Force	5C4145P, 5C4145NS	Manual shut-off clamp closure force on tubing lines shall be no more than 26 lbf.
Clamp Opening Force	5C4145P, 5C4145NS	Manual shut-off clamps on lines shall open with a force no more than 10 lbf.
Bioburden Measurement	5C4145P, 5C4145NS	The drain bag shall have less than or equal to 100 CFUs per set.

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Table 4. Peformance Data		
Test	**Product Code Tested**	**Requirements**
Microbial Travel	5C4145NS	Upper boundaries for bacterial travel distance for both ascending and descending positions at 35-39°C after 48 hours are less than the distance required to contaminate the APD cassette.
Cycler System Level	5C4145NS	For both the HomeChoice and HomeChoice Claria cyclers: Under least favorable conditions, the drain flow rate lower bound > 50ml/min.
Spike Tip Protector Removal Force	5C4145P	The axial force to remove the spike tip protector shall not be less than 4.5 N (1.0 lbf) or greater than 45 N (10.0 lbf).
Pull Ring Tip Protector Removal Force	5C4145P	The axial force to remove the pull ring tip protector shall not be less than 4.5 N (1.0 lbf) or greater than 54 N (12.0 lbf).
Solvent Bond Leak Strength	5C4145P	The subsystem, after being subjected to a 5 lbf pull force shall not leak when subjected to 8 psig pressure for 10 seconds.
Connection Duration Test	5C4145P	Drain bag and APD sets connected after 48 hours.

Biocompatibility:

The biocompatibility evaluation of this product line was conducted in accordance with ISO-10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, as recognized by the FDA. The 15L Cycler Drainage Bags presented in this premarket notification 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 Document Use of International Standard ISO 10993-1: Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process (Issued Sept 4, 2020).

Sterilization:

The sterile version of the 15L Cycler Drainage Bag (5C4145P) is sterilized with ethylene oxide (EO) gas. The product is in the bioburden (sub) category "Bag Device labeled sterile fluid path". The EO cycles used on this product to provide a 10^{-6} Sterility Assurance Level (SAL) for this (sub) category were established and validated at the manufacturing facilities as described in ANSI/AAMI ST67:2019 Sterilization of Health Care Products – requirements and guidance for selecting a sterility assurance level (SAL) for products labeled "sterile". Requirements for products labeled 'sterile' and the sterilization process for the proposed device are also compliant to ANSI/AAMI/ISO 11135-1:2014 Sterilization of Health Care Products – Ethylene Oxide – Part 1:

Requirements for development, validation, and routine control of sterilization process for medical devices.

Shelf Life:

Baxter has performed aging testing to support a shelf-life claim of 5 (five) years.

CONCLUSION:

The non-clinical data demonstrate that the proposed device is substantially equivalent and performs comparably to the predicate device that is legally marketed for the same intended use.