FRESENIUS MEDICAL CARE

JUL 30 2014

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 (FMC-RTG)
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Contact Person:	Denise Oppermann, Senior Director, Regulatory Affairs - Devices
Date of Preparation:	01 May 2014

5.2. Device Name

Trade Name:	Liberty PDx™ Cycler
Common Name:	System, Peritoneal, Automatic Delivery
Classification Name:	Peritoneal dialysis system and accessories
Classification Number:	Class II per 21 CFR §876.5630
Product Code/Classification Panel:	FKX/Gastroenterology/Urology

5.3. Legally Marketed Predicate Device

Fresenius Liberty Cycler (K123630)

5.4. Device Description

The Liberty PDx Cycler is a software-controlled electromechanical device designed for use in Automated Peritoneal Dialysis (APD) therapy for the treatment of end-stage renal disease (ESRD). The Liberty PDx Cycler is designed as a table-top unit for use with single-use, dedicated disposable set (referred to as Liberty PDx Cycler sets). The Liberty PDx Cycler may be prescribed for either clinical or home treatment settings, as the predicate Liberty Cycler. Treatment settings, such as the amount of solution to be infused and the length of time the solution remains in the peritoneal cavity, are programmed into the cycler. During treatment, the Liberty PDx Cycler heats the

peritoneal dialysis solution prior to patient infusion, measures and delivers a predetermined amount of fluid to the patient, and monitors the drained volume.

The Liberty PDx Cycler system consists of a Control Panel (user interface), Pump Module, Cassette Compartment, a disposable Cycler set (single-use), IQdrive, and an optional peripheral cellular modem. The control panel consists of a touchscreen display and front panel keys which provide a user interface. The pump module consists of mushroom-head piston(s) that are linearly displaced to alternately draw the dialysate solution to and from the patient's peritoneal cavity. The cassette compartment provides the interface for the disposable cycler set with the pump module's mushroom-head pistons. The cycler set is connected to a number of tubes which, in turn, connect to the dialysate solution bags, the patient, or a drain and provide a flow path between the cycler and the patient. At the end of each treatment, data generated by the Liberty PDx Cycler and stored in battery-backed memory are read and written to a treatment data set on the IQdrive (USB memory stick). Additionally, an optional peripheral cellular modem can also be used with the Liberty PDx Cycler to transmit treatment data files to an FTP server at the end of each treatment.

The Liberty PDx Cycler set is loaded into the cassette compartment of the Liberty PDx Cycler at the initiation of treatment. The cassette is composed of a ridged molded plastic (polypropylene) body covered with a flexible film/membrane. The cassette contains molded features, such as fluid channels, flexible valve domes and two (2) pumping chambers that are acted upon by the cycler to direct the flow of the peritoneal dialysate to and from the patient's peritoneal cavity.

There are seven (7) fluid lines connected to the cassette:

- One (1) drain line
- One (1) patient connection line (with one (1) or two (2) stay•safe® patient connectors depending on the model)
- Five (5) Dialysate Solution Lines (with Safe-Lock® connector):
  - One (1) heater bag
  - One (1) last dialysate bag/'last bag option'
  - Three (3) additional solution bags

The three Liberty PDx Cycler sets designed for use with the Liberty PDx Cycler are constructed from identical materials. The sets differ only in the length of lines or in the number of patient connectors, as described in Table 1.

Table 1: Liberty PDx Disposable Cycler Sets

Cycler Set Product Codes	Features
050-87220	• Dual Patient Connector • Patient Line - 10 feet • Drain Line – 28 inches
050-87221	• Single Patient Connector • Patient Line - 10 feet • Drain Line - 28 inches
050-87222	• Single Patient Connector • Patient Line - 20 feet • Drain Line - 20 feet

5.5. Indications for Use

The Liberty PDx™ Cycler is indicated for acute and chronic peritoneal dialysis.

5.6. Intended Use

The Liberty PDx™ Cycler is intended for Automated Peritoneal Dialysis (APD) therapy for the treatment of end-stage renal disease (ESRD) in clinical and home settings. The supported peritoneal dialysis therapy types include: Continuous Cycling Peritoneal Dialysis (CCPD), Intermittent Peritoneal Dialysis (IPD), Peritoneal Dialysis Plus™ Therapy (PD+), and Tidal Peritoneal Dialysis (TPD).

5.7. Technological Characteristics

The Liberty PDx Cycler system and the predicate Liberty Cycler have equivalent technological characteristics:

1. **Fundamental Scientific Technology/Operating Principle:** Software-controlled electromechanical pumping system with actuating linear pump heads interfacing with the cassette fluid chamber to direct the flow of dialysis solution between the cycler and the patient. Flow direction is controlled by the pump movement.
2. **Design/Configuration:** Software-controlled electromechanical device with control (pumps and valves) and monitoring (sensors) components which interface with a disposable cycler set for fluid displacement. The single-use disposable cycler set is comprised of dialysate fluid-contacting components such as a pump cassette assembly, male Safe-Lock connectors, tubing, and stay•safe patient connector to allow for the movement of peritoneal dialysate to and from the patient.

3. **User Interface:** Control panel with integrated touchscreen display and front panel keys.
4. **Sterility (Cycler Set):** Ethylene oxide, fluid path only

5.8. Performance Data

Performance testing requirements were determined through the application of a risk management process, applicable FDA guidance documents and performance standards (21 CFR §876.5630). Performance testing to support the determination of substantial equivalence included testing to IEC 60601-2-39:2007, ES 60601-1:2005, IEC 60601-1-2:2007, and IEC 60601-1-11:2010. The Liberty PDx Cycler sets were tested to ISO 10993-1:2009, ISO 10993-7:2008, and ISO 11135-1:2007.

5.9. Conclusion

The information provided in this submission, including design verification, risk management, electrical safety, electromagnetic compatibility (EMC), biocompatibility and usability testing demonstrates the Liberty PDx Cycler functions as intended and supports the determination of substantial equivalence to the predicate device. Test results demonstrate that the differences between the proposed and the predicate device are not significant and do not raise any new concerns with regard to safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 30, 2014

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

Re: K141145
Trade/Device Name: Liberty PDx Cycler
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FKX
Dated: May 1, 2014
Received: May 2, 2014

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Elaine H. Blyskun -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 below.

510(k) Number *(if known)*
K141145

Device Name
Liberty PDx Cycler

Indications for Use *(Describe)*
The Liberty PDx Cycler is indicated for acute and chronic peritoneal dialysis.

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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