May 24, 2018

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

Re: K181108
Trade/Device Name: Fresenius Liberty Select Cycler
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal Dialysis System and Accessories
Regulatory Class: II
Product Code: FKX
Dated: April 26, 2018
Received: April 27, 2018

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,

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)*

K181108

Device Name
Fresenius Liberty Select Cycler

Indications for Use *(Describe)*
The Fresenius Liberty Select 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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:	26 April 2018

5.2. Device Name

Trade Name:	Fresenius Liberty Select Cycler
Common Name:	Peritoneal Dialysis Cycler
Regulation Name:	Peritoneal Dialysis System and Accessories
Regulatory Class:	Class II per 21 CFR §876.5630
Product Code:	FKX
Classification Panel:	Gastroenterology/Urology

5.3. Legally Marketed Predicate Device

The legally marketed predicate device is the Fresenius Liberty Select Cycler (K171652).

5.4. Device Description

5.4.1. Device Identification

The Liberty Select Cycler will be available in the configuration described below.

Product Line	Part Number	Description
Liberty	180343	Liberty Select Cycler

5.4.2. Device Characteristics

The Liberty Select Cycler is an electro-mechanical medical device. Software controls the functions of the machine during peritoneal dialysis treatment, including fluid flow, heating, and alarms.

5.4.3. Environment of Use

The Liberty Select Cycler is prescribed for use in both professional and home treatment settings.

5.4.4. Brief Written Description of the Device

Like the predicate device, the modified Liberty Select Cycler is a software-controlled electro-mechanical medical device designed as a table-top unit to deliver Automated Peritoneal Dialysis (APD) therapy for the treatment of end-stage renal disease (ESRD). The Liberty Select Cycler is used to perform continuous and intermittent peritoneal dialysis therapies. Treatment settings are programmed based on a physician's prescription.

Also like the predicate device, the modified Liberty Select Cycler is compatible with three (3) accessories:

- Cassette and tubing set
- IQdrive
- Optional peripheral wireless modem (AT&T and Verizon 3G/4G LTE networks)

The software has been updated from version 2.8.7 to version 2.8.8 to modify the Patient Line Check (PLC) feature to use a full stroke test to check for a slow-flow or no-flow condition in the patient line during the drain phase. The software changes also modified the soft alarm feature to sound the alarm as soon as a slow-flow or no-flow condition is detected.

5.4.5. Materials of Use

There are no changes to the materials of use from the previous 510(k) submission (K171652). The Liberty Select Cycler enclosure consists of the following materials:

- Plastic housing
- Aluminum heater tray
- Aluminum cassette housing

5.4.6. Essential Performance Characteristics

The Liberty Select Cycler has the same essential performance characteristics as the predicate device (K171652) listed in Table 1.

Table 1: Liberty Select Cycler Essential Performance Characteristics

Feature	Specification
Inflow	45–316 mL/min
Outflow	Minimum: 30 mL/min Maximum: 286 mL/min
Temperature	37°C ± 1°C
Volume Accuracy, Fill	± 2% of the fill volume
Volume Accuracy, Drain	± 3% of the drain volume

5.5. Indications for Use

The Fresenius Liberty Select Cycler is indicated for acute and chronic peritoneal dialysis.

5.6. Comparison of Technological Characteristics with the Predicate Device

There are no changes in the technological characteristics of the previously cleared Liberty Select Cycler (K171652). The modifications to the Liberty Select Cycler pertain only to software.

The following technical specifications of the Liberty Select Cycler remain the same as those of the predicate device:

- Principle of operation
- Environmental requirements
- Accessories
- Transportation and storage specifications
- Hardware specifications
- Manufacturing location

5.7. 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 in compliance with ANSI/AAMI/IEC 62304:2006.

5.7.1. Software Verification and Validation Testing

Unit, software, regression (system verification), exploratory, and validation testing were performed to demonstrate the effectiveness of the software modifications and to confirm operation of the machine.

5.7.2. Mechanical and Acoustic Testing

No mechanical or acoustic tests were performed.

5.7.3. Human Factors Testing

The software modifications from version 2.8.7 to version 2.8.8 did not introduce any new use-related risks or create any changes in the user interface or operation of the Liberty Select Cycler. Labeling modifications involve minor administrative changes with no impact to risk. Therefore, no human factors testing was performed.

5.8. Conclusion

The indications for use, materials of construction, and technological characteristics of the modified Liberty Select Cycler are the same as the predicate device. Differences between the Liberty Select Cycler and the predicate do not raise new concerns with regard to safety or efficacy. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the modified Liberty Select Cycler is substantially equivalent to the predicate device, Liberty Select Cycler (K171652).