October 31, 2022

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

Re: K222318
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: August 1, 2022
Received: August 2, 2022

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. 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

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)*

K222318

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.

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) 996-9103
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann, Senior Director
Preparation Date:	29 July 2022

5.2. Device Name

Trade Name:	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
Product Code Name:	System, Peritoneal, Automatic Delivery
FDA Review Panel:	Gastroenterology/Urology

5.3. Legally Marketed Predicate Device

The legally marketed predicate device is the Fresenius Liberty Select Cycler (K181108). This device has not been subject to a design-related recall.

5.4. Device Description

5.4.1. Device Identification

The Liberty Select Cycler is the subject of this 510(k).

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 (hereinafter referred to as the "Cycler") is a software-controlled electro-mechanical medical device designed to deliver Automated Peritoneal Dialysis (APD) therapy for the treatment of end-stage renal disease (ESRD). The Cycler is designed as a table-top unit that can be used to perform peritoneal dialysis (PD) in hospitals, dialysis clinics, and at home.

The modified Liberty Select Cycler is compatible with the following accessories:

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

The software has been updated from version 2.9.2 to version 3.0.2 to introduce the Remote Therapy Programming feature. This feature allows the Cycler to securely receive prescription settings remotely from a Fresenius server. The remote programming feature streamlines the prescription alteration process because it provides the patient with an alternative to physically bringing their IQdrive (i.e., removable USB drive) to the clinic to receive their prescription settings.

5.4.5. Materials of Use

There are no changes to the materials of use from the previous 510(k) submission (K181108). The Liberty Select Cycler enclosure consists of the following materials:

- Plastic housing
- Aluminum heater tray
- Aluminum cassette housing

5.4.6. Key Performance Specifications/Characteristic

The Liberty Select Cycler has the same essential performance characteristics as the predicate device (K181108) 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 (K181108). The proposed modification to the Liberty Select Cycler pertains only to software.

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

- Principle of operation
- Accessories
- Environmental requirements
- 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/A1:2016* and *ANSI/AAMI/IEC 62366-1:2015*.

5.7.1. Software Verification and Validation Testing

Unit, software, regression (system verification), and validation testing were performed to demonstrate the effectiveness of the software modification and to confirm operation of the machine. Software verification information within this submission is provided in accordance with the following FDA guidance documents:

- *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (11 May 2005)
- *Content of Premarket Submissions for Management of Cybersecurity in Medical Device* (02 October 2014)
- *Design Considerations and Pre-Market Submission recommendations for Interoperable Medical Devices* (06 September 2017)

5.7.2. Human Factors Validation Testing

The Liberty Select Cycler was validated for safe and effective use in accordance with FDA guidance *Applying Human Factors and Usability Engineering to Medical Devices* (06 September 2018) for modifications due to Remote Programming features.

The remaining essential and critical user tasks were determined to be equivalent to the user tasks of the predicate device.

5.8. Conclusion

The information provided in this submission demonstrates the Liberty Select Cycler functions as intended and supports the determination of substantial equivalence to the predicate device, Liberty Select Cycler (K181108).

The Indications for Use, materials of construction, and technological characteristics of the modified Liberty Select Cycler are the same as those of the predicate device. Test results demonstrate that the differences between the proposed and the predicate devices do not raise any new concerns with regard to safety or effectiveness. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the modified Liberty Select Cycler is safe and effective for its intended use.