



Food and Drug Administration
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Silver Spring, MD 20993-0002

September 15, 2017

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

Re: K171652
Trade/Device Name: Fresenius Liberty Select Cyclor
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal Dialysis System and Accessories
Regulatory Class: II
Product Code: FKX
Dated: June 2, 2017
Received: June 5, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) 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>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

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

Indications for Use

510(k) Number (*if known*)
Unknown K171652

Device Name
Fresenius Liberty Select Cyclor

Indications for Use (*Describe*)
The Fresenius Liberty Select Cyclor 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
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02451-1457
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Contact Person: Denise Oppermann, Senior Director
Regulatory Affairs – Devices
Preparation Date: 2 June 2017

5.2. Device Name

Trade Name: Fresenius Liberty Select Cyclor
Common Name: Peritoneal Dialysis Cyclor
Classification Name : System, Peritoneal, Automatic Delivery
Regulatory Class: Class II per 21 CFR 876.5630
Product Code: FKX
Classification Panel: Gastroenterology/Urology

5.3. Legally Marketed Predicate Device

5.3.1. Primary Predicate – Liberty Cyclor (K123630)

The Liberty Cyclor, K123630, will serve as the primary predicate for the Liberty Select Cyclor as described in the 8 September 2016 pre-submission (Q161532).

5.3.2. Secondary Predicate – Liberty PDx Cyclor (K141145)

The Liberty PDx Cyclor will serve as the secondary predicate for the Liberty Select Cyclor.

5.4. Device Description

5.4.1. Device Identification:

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

Product Line	Part Number	Description
Liberty	180343	Liberty Select Cyclor

5.4.2. Device Characteristics

The Liberty Select Cyclor 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 Cyclor is designed as a table-top unit and is prescribed for use in both professional and home treatment settings.

5.4.4. Brief Written Description of the Device

The Liberty Select Cyclor 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 Liberty Select Cyclor is used to perform continuous and intermittent peritoneal dialysis therapies. Treatment settings are programmed based on a physician's prescription. The Liberty Select Cyclor accommodates three (3) accessory devices:

- Cassette and tubing set
- IQdrive
- Optional wireless modem

The cassette and tubing set and the IQdrive are the same accessory devices described in K123630. The peripheral wireless modem has been updated to support AT&T and Verizon 3G/4G LTE networks.

Performance modifications were made to the device. Selectable drain exit criteria and additional STAT Drain options were added. Alarm modifications introduce Soft Alarms that provide the user with an opportunity to correct drain and fill complications before issuing an alarm. The labeling has been modified to align with the software modifications and with the secondary predicate Liberty PDx Cyclor.

5.4.5. Materials of Use

There are no changes to the materials of use from the previous 510(k) submission (K123630).

The Liberty Select Cyclor enclosure consists of the following materials:

- Plastic housing
- Aluminum heater tray
- Aluminum cassette housing

5.4.6. Essential Performance Characteristics

The Liberty Select Cyler has the same essential performance characteristics as the predicate device (K123630) as listed in Table 1.

Table 1: Liberty Select Cyler 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 Cyler is indicated for acute and chronic peritoneal dialysis.

5.6. Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the Liberty Select Cyler are equivalent to the predicate device. Although software modifications were made to improve the user experience, all other electrical components, mechanical components, pump module components, and safety components are identical to the predicate device.

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

- 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 and ANSI/AAMI/IEC 62366-1:2015.

5.7.1. Software Verification and Validation Testing

Unit, integration and system level software verification testing was performed to demonstrate the effectiveness of the software modifications and to confirm operation of the machine.

5.7.2. Mechanical and Acoustic Testing

Mechanical testing was conducted to verify that the Liberty Select Cyclor noise level does not exceed 40 dBA while performing a treatment.

5.7.3. Human Factors Testing

Testing was performed on the modifications found to impact Human Factors:

- Add selectable drain exit criteria (70% or 85%)
- Add selectable additional drain option with option for additional drain alert
- Add STAT drain at the end of the treatment
- Implement soft alarms

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

FMCRTG concludes that the four (4) new features tested on the Liberty Select Cyclor (software version 2.8.7) are safe and effective for the intended users, uses, and use environments.

5.8. Conclusion

The indications for use, materials of construction, and technological characteristics of the Liberty Select Cyclor are the same as the predicate devices. Differences between the Liberty Select Cyclor and the predicates 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 proposed Liberty Select Cyclor is substantially equivalent to the primary predicate device, Liberty Cyclor (K123630).