FRESENIUS MEDICAL CARE

This 510(k) Summary is in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The content of this 510(k) summary conforms with 21 CFR Part 807.92.

Submitter's Information:

Name:	Fresenius Medical Care North America
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
Date of Preparation:	21 November 2012

SEP 09 2013

Device Name:

Trade Name:	**Fresenius Liberty Cycler**
Common Name:	Peritoneal Dialysis Cycler
Product Code/Classification Panel:	FKX / Gastroenterology - Urology
Classification Name:	System, Peritoneal, Automatic Delivery Class II per §876.5630

Legally Marketed Predicate Device (unmodified device):

Fresenius Liberty Cycler (K043363)

Device Description:

The Liberty Cycler is a computer-controlled electro-mechanical medical device designed for use in Automated Peritoneal Dialysis (APD) therapy for the treatment of end-stage renal disease (ESRD). The Liberty Cycler design incorporates software-controlled pumping action for fluid movement. The Liberty Cycler heats the peritoneal dialysate solution prior to user infusion,

measures and delivers a pre-determined amount of fluid to the user and monitors the drained volume from the user.

The Liberty Cycler is designed as a table-top unit and is prescribed in both professional and home treatment settings.

Modifications to the predicate Liberty Cycler include changes to the performance specifications to allow use of a 6-liter dialysate solution bag. The Liberty Cycler can now accommodate a 1 to 6-liter dialysate solution bag configuration. **Additional modifications are included in this submission which are intended to enhance performance and data management within predicate specifications.**

Indications for Use:

The Fresenius Liberty Cycler is indicated for acute and chronic peritoneal dialysis. There is no change to the indications for use.

Technological Characteristics:

The design and technological characteristics of the Liberty Cycler device described within this submission are identical to the predicate Liberty Cycler (K043363), with the exception of the change to accommodate a 6-liter dialysate solution bag and other modifications to enhance performance and data management within predicate specifications.

A risk analysis has been completed and potential hazards associated with the modifications were identified and mitigated. Mitigations are verified wherever applicable. Performance and safety tests were conducted to ensure the safety and effectiveness of the device after the proposed modifications.

Performance Data:

The performance of the modified Liberty Cycler was evaluated according to existing Fresenius Medical Care procedures, protocols, and declared performance standards and guidelines of the quality system regulation (21 CFR 820). Design verification and validation tests were conducted to ensure that the modifications described in this submission did not affect the essential performance of the device and the device functions as intended.

The following testing was conducted:

- Full system validation and software testing, including:
  - Software validation and regression testing
  - System performance testing using the 6-liter dialysate solution bag

Test results demonstrated that all modifications functioned as intended and met pre-determined acceptance criteria. The essential performance of the Liberty Cycler is not affected by the modifications.

- Human factors (usability) testing according to IEC 62366 Application of usability engineering to medical devices. The modified Liberty Cycler met prescribed criteria.
- Electrical safety testing (UL 60601-1, 1st Edition, 2006-04-26, (Medical Electrical Equipment, Part 1: General Requirements for Safety)). The modified Liberty Cycler was found to comply with the standard.
- Peritoneal dialysis device performance testing (IEC 60601-2-39: 1999 (First Edition) for use in conjunction with IEC 60601-1, 1st Edition, 2006-04-26). The modified Liberty Cycler complied with the standard.
- Electromagnetic compatibility testing (EMC; IEC 60601-1-2 (2007), Class B testing criteria). The modified Liberty Cycler complied with the standard.

Conclusion:

The performance data demonstrate that the Liberty Cycler is as safe and effective, and performs as well as the predicate device.

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

September 9, 2013

Fresenius Medical Care - North America
% Denise Oppermann
Senior Director, Regulatory Affairs - Devices
920 Winter Street
Waltham, MA 02451

Re: K123630
Trade/Device Name: Fresenius Liberty Cycler
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: Class II
Product Code: FKX
Dated: August 23, 2013
Received: August 26, 2013

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 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. 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,

Herbert P. Lerner -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

510(k) Number (if known): K123630

Device Name:

Fresenius Liberty Cycler

Indications for Use:

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

☒ Prescription Use (Per 21 CFR 801 Subpart D)

AND/OR

☐ Over-the-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S