April 15, 2022

Fresenius Medical Care Renal Therapies Group, LLC
Denise M. Oppermann
Senior Director, RA Devices
920 Winter Street
Waltham, MA 02451

Re: K212522
Trade/Device Name: Lilliput™ APD System
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FKX
Dated: March 11, 2022
Received: March 14, 2022

Dear Denise M. 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
Glenn B. Bell, Ph.D.
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)*

K212522

Device Name

Lilliput™ APD System

Indications for Use *(Describe)*

The Lilliput™ APD System is indicated for adult chronic peritoneal dialysis in home and clinical settings

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:	10 August 2021

5.2. Device Name

Trade Name:	Lilliput™ APD System
Common Name:	System, Peritoneal, Automatic Delivery
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 devices are the Liberty PDx Cycler cleared under K141145 and the Fresenius Liberty Select Cycler cleared under K181108.

5.4. Device Description

5.4.1. Device Identification

The Lilliput APD System is available in one (1) configuration that includes an electromechanical cycler (hereinafter referred to as "Cycler"), disposable set (hereinafter referred to as "Disposable Set"), USB key, and Kinexus Gateway. The Disposable Sets are available in three (3) configurations:

- Lilliput Disposable Set, One Patient Connector (Low feature)
- Lilliput Disposable Set, One Patient Connector with Extended Drain and Patient Lines (Medium Feature)
- Lilliput Disposable Set, Two Patient Connectors with Extended Drain and Patient Lines (High Feature)

5.4.2. Device Characteristics

The Cycler is a software-controlled electromechanical medical device. The Disposable Sets are single-use Class II devices designed to operate with the Cycler to perform Automated Peritoneal Dialysis (APD) therapy for the treatment of end-stage renal disease (ESRD). The Disposable Sets are provided sterile and non-pyrogenic and are sterilized using ethylene oxide (EO).

5.4.3. Environment of Use

The Lilliput APD System is prescribed for use in both professional and home healthcare settings

5.4.4. Brief Written Description of the Device

The Lilliput APD System includes a Cycler, Disposable Set, USB Key, Kinexus Gateway, and optional accessories that are designed for use with the Cycler or Disposable Set. The Lilliput APD system components are described in Table 1.

Table 1: Lilliput APD System Components Description

Component	Description
Cycler	Software-controlled electromechanical device
User Interface	Touchscreen display and front panel keys which enable user interaction with the Cycler
Disposable Set	Composed of a cartridge and flexible tubing lines used for exchange of fluid between the dialysate bag, patient, and drain. The cartridge contains the functional components of the peristaltic pump that interface with the Cycler to enable fluid exchange.
Cartridge Loader	Motorized loading mechanism that enables the interface between the Cycler and Disposable Set by moving the cartridge into place when it is inserted into the Cycler
Pump System	Composed of a peristaltic pump and pump motor • Peristaltic pump: Formed by the mechanical coupling of the pump drive (with rotating shaft) in the Cycler and the pump head in the cartridge • Pump motor: Electromechanical motor that rotates the Cycler pump drive
Warmer	Heats dialysate solution prior to solution flow to the patient
USB Key	Memory device used by both patients and clinical staff to store and transfer prescription and treatment data to and from the cycler
Kinexus Gateway	Allows communication between the Lilliput APD System, off-the-shelf (OTS) peripheral devices, and remote data storage services

Table 1: Lilliput APD System Components Description

Component	Description
Optional Accessories	Optional accessories designed for use with the Cycler or Disposable Set (e.g., cart, travel case, solution bag case)

The Cycler is a software-controlled electromechanical device designed for use in APD therapy for the treatment of ESRD. The software controls the functions of the Cycler during peritoneal dialysis (PD) treatment. The Cycler is designed as a table-top unit for use with a single-use, dedicated disposable set. The Lilliput APD System may be prescribed for either clinical or home treatment settings. 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 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 Lilliput Disposables Sets are used as accessories to the Cycler. The Disposables sets are composed of a cartridge and, depending on the configuration, 7 or 8 fluid lines. The fluid lines consist of:

- 1 drain line (4 feet or 20 feet, depending on the configuration) with a female Luer-lock connector.
- 1 patient connection line (with 1 or 2 stay•safe® patient connectors, depending on the configuration)
- 2 warming pouch lines (1 warmer return line and 1 warmer inlet line)
- 2 or 3 dialysate bag lines (with Safe-Lock® connectors), depending on the configuration.
- 1 last bag inlet line

When used in conjunction with the Cycler, the Disposable Sets provide a defined, sterile fluid path with secure connections (stay•safe, Safe-Lock, and Luer lock) to alternately draw the prescribed dialysate solution to and from the patient's peritoneal cavity.

5.4.5. Materials of Use

5.4.5.1. Cycler

The materials of use for the Cycler are provided in Table 2.

Table 2: Lilliput Cycler Materials

Component	Material
Cycler Housing	Plastic (PC/ABS Cycoloy C6600)
Warmer	Foil heating plates
Cartridge Loader	Aluminum/Plastic (PC/ABS Cycoloy C6600)

5.4.5.2. Disposable Sets

The Disposable Sets are classified as externally communicating, blood path indirect, prolonged contact (>24 hours to 30 days) duration, Class II (Category B) devices in accordance with FDA guidance document, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* (04 September 2020).

With the exception of the cartridge and warming pouch components, the 3 Disposable Sets are constructed from materials identical to those of the predicate device.

Materials used in the manufacture of the Disposable Sets are detailed in Table 3.

Table 3: Disposable Set Materials of Use

Component	Materials
Cartridge	Silicone Polycarbonate (PC) Polyamide 12 (PA12)
Tubing and Connectors	Polyvinyl chloride (PVC) Acrylic polymer Polypropylene (PP) Silicone PC
Warming Pouch	PVC PC
Clamps	High-density polyethylene (HDPE) PP
Connector Caps	Ethylene-vinyl acetate (EVA) PP Polyethylene (PE)
Solvents	Cyclohexanone

5.4.6. Key Performance Specifications/Characteristic

The Lilliput essential performance requirements are provided in Table 4.

Table 4: Lilliput Essential Performance

Feature	Specification
Dialyzing solution flow rate during inflow	150–300 mL/min
Dialyzing solution flow rate during outflow	100–250 mL/min
Dialyzing solution volume balancing (inflow volume) (**FILL**)	Volume accuracy is the larger of (at 2X standard deviation): ≤±15 mL or ±5%
Dialyzing solution volume balancing (outflow volume) (**DRAIN**)	Volume accuracy is the larger of (at 2X standard deviation): ≤±15 mL or ±5%
Volume Balancing (Symmetric Volume Accuracy)	Symmetric volume accuracy is the larger of (at 2X standard deviation): ≤±12 mL or ±2%
PD dwell time	Dependent on prescription. Dwell time accuracy ± 1 minute for the calculated dwell time
Dialyzing solution temperature	37°C±2°C

5.5. Intended Use

The Lilliput APD System 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+), Tidal Peritoneal Dialysis (TPD), Nocturnal Intermittent Peritoneal Dialysis (NIPD) and adapted Automated Peritoneal Dialysis (aAPD).

5.6. Indications for Use

The Lilliput™ APD System is indicated for adult chronic peritoneal dialysis in home and clinical settings.

5.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the Lilliput APD System are substantially equivalent to the primary predicate device Liberty PDx Cycler (K141145) and secondary predicate Liberty Select Cycler (K181108):

- Intended Use
- Indications for Use
- Fundamental Scientific Technology/Operating Principle
- Technological Characteristics
- Essential Performance Requirements
- Sterilization Method, Packaging, and Sterility Label Claims (Disposable Set)

5.8. Sterilization Testing (Disposable Sets)

The Disposable Sets are sterilized by exposure to 100% ethylene oxide (EO). The sterility assurance level (SAL) is 10^{-6}. Sterility and non-pyrogenicity are claimed for the fluid pathway of the disposable set.

5.8.1. EO Residual Testing

Residual testing for EO and ethylene chlorohydrin (ECh) was performed in accordance with *AAMI/ANSI/ISO 10993-7:2008/(R) 2012 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*. Acceptable results (i.e., <4.6 mg/device for EO and ECh) were obtained for the subject disposable sets.

5.8.2. Bacterial Endotoxin (Pyrogenicity) Testing

The Disposable Sets were tested for bacterial endotoxin (pyrogenicity) with Limulus Amebocyte Lysate (LAL) in accordance with *ANSI/AAMI/ST72:2019 Bacterial Endotoxins – Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing*. It was determined the Disposable Sets are non-pyrogenic (<20 EU/device).

5.8.3. Sterile Barrier Testing

Sterility of the Lilliput Disposable Sets' fluid pathway is maintained by the device itself. This includes vented caps with connectors (vented tortuous path or hydrophobic membrane/filter), tubing, and the cartridge portion of the Disposable Set.

The vented caps were qualified as part of the sterile barrier by microbial challenge tests in accordance with ANSI/AAMI/ISO 11607-1.

The tubing and other components were qualified as part of the sterile barrier through leak testing and the structural integrity test adapted from ISO 8638. Testing was performed on samples after aging and distribution simulation.

5.9. Performance Data

5.9.1. Cycler Performance Testing Summary

Testing conducted to support the determination of substantial equivalence for the Cycler is provided in Table 5.

Table 5: Cycler Performance Testing Summary

Test Conducted	Test Method Description
Simulated Treatments	Simulated peritoneal dialysis treatments were performed in a simulated patient use environment.
Essential Performance	Simulated peritoneal dialysis treatments were performed in a simulated patient use environment. System essential performance was verified during simulated peritoneal dialysis treatments
System and Cycler Subsystem and Functional Design Verification	System functional requirements including user interface, solution management, pressure sensors, pumping system, and heating were verified according to pre-determined performance specifications.
Operational Environment	System operational environment performance was verified under simulated operational environment conditions.
Safety System	System safety requirements including alarms, solution flow stoppage, and sensor functionality were verified according to pre-determined performance specifications
Shipping and Packaging	Shipping and packaging verification according to ASTM D4169-16 and ASTM D7386-16

5.9.2. Lilliput Disposable Set Performance Testing

Testing conducted to support the determination of substantial equivalence for the Disposable Set is provided in Table 6.

Table 6: Lilliput Disposable Set Performance Testing Summary

Test Conducted	Test Method Description
Performance Test: Load to close the tubing clamp	The maximum load force (lbf) to close the Lilliput clamp was determined using a calibrated electromechanical force gauge (Instron Machine)
Performance Test: Load to push the stay•safe PIN connector	The maximum load force (lbf) required for the PIN (Trigger plunger) from the stay•safe PIN connector to insert into a catheter connector was determined using a calibrated electromechanical force gauge (Instron Machine)

Table 6: Lilliput Disposable Set Performance Testing Summary

Test Conducted	Test Method Description
Occlusion test	The ability of the patient, solution, and drain line clamps to occlude the patient, solution lines, and drain line was determined by subjecting to a positive pressure of 1 bar at 15°C or 39°C for 10 min and observing for leakage of air bubbles.
Compression test	The maximum load force (lbf) that the cartridge ports must withstand was determined using a calibrated electromechanical force gauge (Instron Machine)
Bond Strength	A calibrated electromechanical force gauge (Instron Machine) was used to perform a pull-off test for each bonded engagement
Shipping Test	A simulated shipping and distribution test was conducted per *ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems*, Distribution Cycle 6, Assurance Level II to ensure that the product's structural integrity is maintained during shipping
Heater Bag Seal	The ability of the heater bag (warming pouch) material to withstand pressure was determined by subjecting it to positive pressure of 1 bar at 39°C for 10 min and observing for leaks or pressure decay
Structural Integrity	The ability of the disposable sets to withstand 1.5X the labeled maximum positive and negative pressures was determined

5.9.3. Biocompatibility Testing

Biocompatibility testing was conducted in accordance with ISO 10993-1:2018 and FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices –Part 1: Evaluation and testing within a risk management process"* (04 September 2020). The following endpoints were evaluated to support the biological safety of the Lilliput Disposable Sets.

- Semi-quantitative Leachable Chemical Evaluation, 1.5% Dextrose, 4.25% Dextrose and 7.5% Icodextrin (Volatiles, Semi-Volatiles, Non-Volatiles, Metals, and Elements)
- Cytotoxicity
- Sensitization
- Irritation
- Material-Mediated Pyrogenicity
- Hemocompatibility
- Systemic Toxicity

- Genotoxicity

A Toxicological Risk Assessment was also performed.

5.9.4. Human Factors Validation Testing

The Lilliput APD System was validated for safe and effective use in accordance with FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices* (03 February 2016).

5.9.5. Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical Safety testing was performed in accordance with IEC 60601-1:2005. Electromagnetic Compatibility testing was performed in accordance with IEC 60601-1-2:2014. Electromagnetic Compatibility information within this submission is provided in accordance with FDA guidance document *Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices* (11 July 2016).

5.9.6. Software Verification and Validation Testing

Unit, software, regression (system verification), and validation testing were performed to demonstrate the effectiveness of the software 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)
- Guidance for Off-The-Shelf Software Use in Medical Devices (27 September 2019)
- Content of Premarket Submissions for Management of Cybersecurity in Medical device (02 October 2014)
- Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software (14 January 2005)
- Design Considerations and Pre-Market Submission recommendations for Interoperable Medical Devices (06 September 2017)

5.9.7. Animal Studies

No animal studies were conducted.

5.9.8. Clinical Studies

No clinical studies were conducted.

5.10. Conclusion

The information provided in this submission, including design verification, risk management, electrical safety, electromagnetic compatibility (EMC), biocompatibility, and usability testing, demonstrates the Lilliput APD System functions as intended and supports the determination of

substantial equivalence to the predicate devices. 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.

The Indications for Use, technological characteristics, design, and performance requirements of the Lilliput APD System are substantially equivalent to those of the predicate devices. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the Lilliput APD System is safe and effective for the intended use.