February 9, 2022

CloudCath
Brian Fisher
Chief Operating Officer
665 3rd Street, Suite 250
San Francisco, California 94107

Re: K212658
Trade/Device Name: CloudCath Peritoneal Dialysis Drain Set Monitoring System
Regulation Number: 21 CFR 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FKX
Dated: January 4, 2022
Received: January 10, 2022

Dear Brian Fisher:

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,

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)*
K212658

Device Name
CloudCath Peritoneal Dialysis Drain Set Monitoring System (also known as the CloudCath System)

Indications for Use *(Describe)*
The CloudCath System is intended for patients undergoing acute and chronic peritoneal dialysis.

The CloudCath System enables drainage and measures turbidity, reported as a numeric score, in peritoneal dialysate effluent as a supplement to visual examination of cloudiness in dialysate drain lines. The system is indicated for use by patients undergoing continuous cycling peritoneal dialysis (CCPD) in a healthcare facility or at home. The optical sensor has associated hardware and software components to allow for data transmission to a healthcare professional.

This system is not intended to provide diagnostic information and is not intended to be a substitute for good clinical management practices, nor does its operation create decisions or treatment pathways.

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.

Section 5: 510(k) Summary

This summary is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Owner Information:

CloudCath
665 3rd St, Suite 250
San Francisco CA 94107
(415) 484-4896

Submission Correspondent:

Brian Fisher
Chief Operating Officer
(415) 651-3393
Brian@CloudCath.com

Device Information:

Trade Name:	CloudCath Peritoneal Dialysis Drain Set Monitoring System
Common Name:	Peritoneal dialysis drain set monitoring device
Regulation:	21 CFR 876.5630
Classification Panel:	Gastroenterology and Urology
Device Type:	Peritoneal dialysis system and accessories
Device Class:	II
Product Code:	FKX

Predicate Device:

Trade/Device Name: Liberty Cycler and Disposable Cycler Set

Manufacturer: Fresenius Medical Care Renal Therapies Group, LLC

Regulation Number: 21 CFR§ 876.5630

Regulation Description: Peritoneal Dialysis System and Accessories

Device Class: II

Product Code: FKX

510(k) Number: K043363

510(k) Clearance date: March 31, 2005

Date Prepared:

August 18, 2021

Device Description:

The CloudCath Peritoneal Dialysis Drain Set Monitoring System (CloudCath System) is a tabletop passive drainage system used as an attachment during a peritoneal dialysis (PD) treatment and indicated for use by patients with acute and chronic end-stage renal disease undergoing PD. The CloudCath System connects directly to the end of the cycler tubing set drain line in order to enable draining and contains an optical sensor that measures turbidity, reported as a turbidity score, in peritoneal dialysate effluent as a supplement to visual examination of cloudiness in dialysate drain lines. The system is indicated for use with validated peritoneal dialysis cyclers in healthcare facilities or home use environments. The optical sensor has associated hardware and software components to allow for remote data transmission by healthcare providers.

The CloudCath System is comprised of three main components: Sensor, Drain Set and Patient Monitoring Software. The Drain Set and the Sensor are components used by the patient. The Patient Monitoring Software is a cloud-based system used by a healthcare professional to view the results from the patient's use of the CloudCath System.

Intended Use / Indications for Use:

The CloudCath System is intended for patients undergoing acute and chronic peritoneal dialysis.

The CloudCath System enables drainage and measures turbidity, reported as a numeric score, in peritoneal dialysate effluent as a supplement to visual examination of cloudiness in dialysate drain lines. The system is indicated for use by patients undergoing continuous cycling peritoneal dialysis (CCPD) in a healthcare facility or at home. The optical sensor has associated hardware and software components to allow for data transmission to a healthcare professional.

This system is not intended to provide diagnostic information and is not intended to be a substitute for good clinical management practices, nor does its operation create decisions or treatment pathways.

Comparison of Intended Use, Indications for Use and Technological Characteristics with the Predicate Devices:

Similar to the Liberty Cycler and Disposable Cycler Set (the predicate device), the CloudCath System is intended for use by patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis in a healthcare facility or at home. Results of testing demonstrated that the differences in the design, materials and function of the subject device do not raise different questions of safety and effectiveness and; therefore, the subject device is substantially equivalent to the predicate device.

Substantial Equivalence Table

	Subject Device **CloudCath System**	**Predicate Device** **Liberty Cycler and Disposable Cycler Set** **K043363**	**Equivalence**
Regulatory Classification / Product Code	21 CFR §876.5630 Peritoneal Dialysis System and Accessories / FKX	21 CFR §876.5630 Peritoneal Dialysis System and Accessories / FKX	SAME
Indications for Use	The CloudCath System is intended for patients undergoing acute and chronic peritoneal dialysis. The CloudCath System enables drainage and measures turbidity, reported as a numeric score, in peritoneal dialysate effluent as a supplement to visual examination of cloudiness in dialysate drain lines. The system is indicated for use by patients undergoing continuous cycling peritoneal dialysis (CCPD) in a healthcare facility or at home. The optical sensor has associated hardware and software components to allow for data transmission to a healthcare professional. This system is not intended to provide diagnostic information and is not intended to be a substitute for good clinical management practices, nor does its operation create decisions or treatment pathways.	…is indicated for acute and chronic peritoneal dialysis.	SAME – Both devices are indicated for use by patients undergoing acute and chronic peritoneal dialysis.
Rx or OTC	Rx	Rx	SAME
Use Environment	Table-top unit in healthcare and home environments	Table-top unit in healthcare and home environments	SAME
Patient Population	Patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD)	Patients with acute and chronic end-stage renal disease undergoing peritoneal dialysis (PD)	SAME
Usability	Sensor: Multi-use Drain Set: Single Use	Cycler: Multi-use Cycler Set: Single Use	SAME
Sterilization	Sensor: Not provided sterile Drain Set: Provided sterile	Cycler: Not provided sterile Cycler Set: Provided sterile	SAME
Power Source	Grounded AC Wall Outlet	Grounded AC Wall Outlet	SAME
Mechanism of Action: Treatment	None, accessory device	Administration of dialysate	Does not raise different questions of safety or effectiveness, as no treatment is being performed by subject device.

	Subject Device CloudCath System	**Predicate Device Liberty Cycler and Disposable Cycler Set K043363**	**Equivalence**
Mechanism of Action: Sensing and Monitoring	Turbidity Monitoring through Optical Sensing	Ultrafiltration Volume and Overfill Monitoring through Pressure Sensing	Both devices use a sensing technology to measure a parameter of relevance during dialysis for the same patient population; therefore, they do not raise new questions of safety and effectiveness.
Wireless Data Transfer	Turbidity data to the HCP	Ultrafiltration and Overfill (including patient entered vitals) data to the HCP	SAME – Sensors provide data to the HCP
Electrical Safety Testing	IEC 60601-1 and IEC 60601-1-11 Testing	Assume Electrical Safety Testing Completed	Presumably SAME, per FDA Recognized Standard
EMC Testing	IEC 60601-1-2 Testing	Assume EMC Testing completed	Presumably SAME, per FDA Recognized Standard
Software V/V Testing	Testing in conformance with IEC 62304	Assume Software V/V completed	Presumably SAME, per FDA Recognized Standard
Usability Testing	Testing in conformance with IEC 62366-1	Assume Usability Testing completed	Presumably SAME, per FDA Recognized Standard
Cybersecurity (Data Transmission)	Design/testing utilizing FDA Cybersecurity Guidance (2014)	Unknown	Presumably SAME, per FDA Guidance
Performance Testing (Mechanism of Action)	Optical Sensor Testing and System Validation Testing	Functional, System Validation and release testing completed	Differences supported by Performance Testing – Bench (see Section 18)
Fluid Contacting Material	Polyvinyl Chloride (PVC) Co-polyester	Materials similar to other peritoneal dialysis systems	Similar
Biocompatibility	Not applicable - "non-contact" ISO 10993-1 Classification	Assume Biocompatibility testing complete	Not required per 10993-1 classification for the CloudCath System as the device is not patient contacting, but mitigation testing was performed to confirm no drain fluid backflow. Subject device use is limited to cyclers with backflow mitigation measures.
Principal of Operation	…is used to enable effluent drainage as needed during the drain phase of an Automated Peritoneal Dialysis (APD) treatment.	…is used to enable effluent drainage as needed during the drain phase of an Automated Peritoneal Dialysis (APD) treatment.	SAME
Connections	…connects to the cycler set drain line and drainage receptacle.	Disposable Cycler Set connects to cycler, patient catheter and drainage receptacle	SAME

Non-Clinical Performance Testing

Non-clinical performance testing demonstrated that the CloudCath System is safe and effective in monitoring the peritoneal dialysis fluid during a peritoneal dialysis treatment. The determination of substantial equivalence was based on an assessment of the results from this testing. The table below is a summary of the non-clinical performance testing which was performed. All tests were successfully completed and did not raise any different questions of safety or effectiveness.

Type of Testing Performed	Methods / Standards Used	Results / Conclusions
Packaging performance and aging testing (Drain Set, Sensor)	ASTM D4332, ASTM D4169, ASTM F1980	Pass / Did not raise any different questions of safety or effectiveness
Functional performance testing (mechanical characteristics and structural integrity testing)	Visual inspection, clamp test, leak test, tensile test, kink test, pressure test	Pass / Did not raise any different questions of safety or effectiveness
Maintenance of sterile fluid path (sterility) testing (Drain Set)	Microbial aerosol challenge test per ISO 11607-1	Pass / Did not raise any different questions of safety or effectiveness
Dimensional verification testing (Engineering Analysis and Type Testing)	Verification of device features including inner diameter, outer diameter and durometer	Pass / Did not raise any different questions of safety or effectiveness
Complete system performance validation	End-to-end performance testing of complete CloudCath System in simulated-use environment	Pass / Did not raise any different questions of safety or effectiveness
Cycler compatibility testing of CloudCath System	Compatibility testing of CloudCath System with compatible cyclers (Force-to-connect test, compatibility testing with and without CloudCath System, backflow, and variety of flow settings test)	Pass / Did not raise any different questions of safety or effectiveness
Hardware fatigue/aging testing	Fatigue testing of Sensor and Drain Set	Pass / Did not raise any different questions of safety or effectiveness
Electrical safety and EMC testing	Compliance testing per IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11	Pass / Did not raise any different questions of safety or effectiveness
Analytical Performance testing of turbidity measurements	Testing to verify turbidity measurements to ensure limits of detection, bias, and precision. Also included static and dynamic flow testing	Pass / Did not raise any different questions of safety or effectiveness
Method Comparison testing using clinical samples	Testing to verify turbidity measurements by comparability to a comparative method using clinical samples	Pass / Did not raise any different questions of safety or effectiveness
Reference Intervals/Ranges (Expected Values) testing	Establishing reference intervals/ranges of the CloudCath System Turbidity Score with clinical samples	Pass / Did not raise any different questions of safety or effectiveness
Electrical aging testing	Evaluation of aging of the measurement systems of the Sensor	Pass / Did not raise any different questions of safety or effectiveness
Human factors / usability testing	Formative and summative evaluations of CloudCath System in accordance with ISO 62366 and FDA Guidance	Pass / Did not raise any different questions of safety or effectiveness

Conclusion

The CloudCath System is a Peritoneal Dialysis Drain Set Monitoring Device per 21 CFR 876.5630 and Product Code FKX. It has the same intended use and similar technological characteristics as the predicate device, the Liberty Cycler and Disposable Cycler Set (K043363). The differences between the CloudCath System and the predicate were determined to not raise different questions of safety and effectiveness and testing demonstrated that the CloudCath System is as safe and effective as the predicate device. Therefore, the CloudCath System is concluded to be substantially equivalent to the predicate device.