October 2, 2025

Simergent, LLC
Steve Lindo
CEO & Co-Founder
11 NE 11th Street, Suite 229
Oklahoma City, OK 73104

Re: K250523
Trade/Device Name: Archimedes Pro Automated Peritoneal Dialysis Cycler (3014-00000-1); Archimedes Standard Automated Peritoneal Dialysis Cycler (3014-00000-3); Archimedes Pro Disposable Tubing Set (3014-50000-1); Archimedes Standard Disposable Tubing Set (3014-50000-3); Archimedes Pro Plus Disposable Tubing Set (3014-50000-5)
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FKX
Dated: September 2, 2025
Received: September 2, 2025

Dear Steve Lindo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Maura Rooney -S

Maura Rooney
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250523

Device Name

Archimedes Pro Automated Peritoneal Dialysis Cycler (3014-00000-1);
Archimedes Standard Automated Peritoneal Dialysis Cycler (3014-00000-3);
Archimedes Pro Disposable Tubing Set (3014-50000-1);
Archimedes Standard Disposable Tubing Set (3014-50000-3);
Archimedes Pro Plus Disposable Tubing Set (3014-50000-5)

Indications for Use *(Describe)*

The Archimedes APD system is an Automated Peritoneal Dialysis system indicated for acute and chronic peritoneal dialysis for adult patients in clinical and home use. A care partner is not required. The following therapies are supported: Continuous Cyclic Peritoneal Dialysis (CCPD) and Intermittent Peritoneal Dialysis (IPD). Mid-day exchanges are not supported.

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.

Traditional 510(k) Summary

1. **Summary Date:** February 7, 2025

2. **Applicant Name:** Simergent, LLC
11 NE 11th St Suite 229
Oklahoma City, OK 73104
Website: https://www.simergent.com
Owner/Operator Number: Pending

3. **Submission Correspondent:** On behalf of Simergent, the following person is assigned the responsibility of submission correspondence:
Steve Lindo, CEO & Co-Founder
12920 S. 82nd Ct
Palos Park, IL 60464
Ph: 214-557-5868

4. **Authorized Correspondent**: On behalf of Simergent, the following consultant is authorized to correspond with the agency regarding this submission:
John F. Ziobro, Principal Consultant
SpectraMedEx, LLC
3215 Golf Drive, #149
Delafield, WI 53018
Ph: 262-719-8922
email: jfz@spectramedex.com

5. **Trade Name:** Archimedes

6. **Model Numbers:** Automated Peritoneal Dialysis Cycler
3014-00000-1 Archimedes Pro
3014-00000-3 Archimedes Standard

Archimedes Disposable Tubing Set
3014-50000-1 Archimedes Pro
3014-50000-3 Archimedes Standard
3014-50000-5 Archimedes Pro Plus

7. **Suggested Classification Regulation, Class, Product Code, Description & Panel:**

Regulation #	Class	Product Code	Description	Review Panel
21 CFR 876.5630	II	FKX	Peritoneal dialysis system and accessories	Gastroenterology and Urology

8. **Reason for Traditional 510(k):** New Submission (No previous submissions)

9. **Predicate Device(s):** Fresenius PD+ *IQCard* Cycler and CCPD Cycler Set W/5 Pronged Safe Lock

10. **Predicate 510(k) Number:** K002892 and K822549

11. **Predicate Manufacturer:** Fresenius Medical Care
Website: https://fmcna.com/
Owner/Operator Number: 1225714

12. **Predicate Classification Regulation, Class, Product Code, Description & Panel**
Both predicate devices have the same Classification Regulation, Class, Product Code, Description & Panel.

Regulation #	Class	Product Code	Description	Review Panel
21 CFR 876.5630	II	FKX	Peritoneal dialysis system and accessories	Gastroenterology and Urology

13. **Proposed Indication for Use:**
The Archimedes APD device is an Automated Peritoneal Dialysis system indicated for acute and chronic peritoneal dialysis for adult patients in clinical and home use. A care partner is not required. The following therapies are supported: Continuous Cyclic Peritoneal Dialysis (CCPD) and Intermittent Peritoneal Dialysis (IPD). Mid-day exchanges are not supported.

14. **Guidance Documents/Special Control/Regulations**
The recognized consensus standards under 21 CFR 876.5630 which are applicable to the proposed device are as follows:
    - 9-149 IEC 60601-2-39 Edition 3.0 2018-04

    The following FDA guidance documents were applied to the design and software verification of the proposed device:
    - Content of Premarket Submissions for Device Software Functions (June 14, 2023)
    - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (September 27, 2023)
    - Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016)
    - Design Considerations for Devices Intended for Home Use (November 24, 2014)

    The following FDA guidance document was applied to the design and biocompatibility verification of the proposed device:
    - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (September 8, 2023)

    The following FDA guidance document was applied to the design and sterility verification of the proposed device:
    - Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile (January 8, 2024)
    - Guidance for Industry Pyrogen and Endotoxins Testing: Questions and Answers (June 2012)

15. **Device Description:**
The proposed system is an automated peritoneal dialysis (APD) cycler which consists of a heater unit, control unit, cart, drain containers, and disposable tubing set.

16. **Materials:**
The cycler consists of the following materials:
    - Plastic housing
    - Aluminum heater tray
    - Steel cart

    The disposable tubing set consists of the following materials:
    - Plastic tubing
    - Plastic connectors

17. **Human Factors Validation Testing:**
The Archimedes cycler was validated for safe and effective use in accordance with FDA guidance Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016).

18. **Comparison of Technological Characteristics with the Predicate Device:**
The Archimedes cycler has similar technical characteristics as those of the predicate device. Basic principle of operation (gravity fill/drain via software-controlled valves), use of vertically-oriented mobile cart/stand, fluid measurement mechanism (scales), fluid heating mechanism (AC-powered resistive heater), and volumetric accuracy for fill and drain are all similar to the predicate device.

The Archimedes disposable tubing set has similar technical characteristics as those of the predicate device. Basic principle of operation (gravity fill/drain fluid control via pinch valves), use of materials, connection methods, interactions with third party devices, and sterility are all similar to the predicate device.

19. **Comparison Summary / Conclusions**
Simergent believes the proposed Simergent Archimedes device under review and the predicate device Fresenius PD+ IQCard Cycler cleared under K002892 are substantially equivalent. Furthermore, both devices have the same/equivalent technological characteristics, physical characteristics and safety standards. The differences that exist between the devices do not affect the relative safety and/or effectiveness.

Additionally, Simergent believes the proposed Simergent Archimedes device (disposable tubing set) under review and the predicate device Fresenius CCPD Cycler Set W/5 Pronged Safe Lock cleared under K822549 are substantially equivalent. Furthermore, both devices have the same/equivalent technological characteristics, physical characteristics and safety standards. The differences that exist between the devices do not affect the relative safety and/or effectiveness.