December 4, 2023

Outset Medical, Inc.
Claire Bao
Senior Regulatory Affairs Specialist
3052 Orchard Drive
San Jose, California 95134

Re: K233335
Trade/Device Name: Tablo® Hemodialysis System
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: Class II
Product Code: KDI, FIP
Dated: September 28, 2023
Received: September 29, 2023

Dear Claire Bao:

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.

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

Digitally signed by Maura Rooney -S
Date: 2023.12.05 09:53:57 -05'00'

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.

510(k) Number *(if known)*
K233335

Device Name
Tablo® Hemodialysis System

Indications for Use *(Describe)*
The Tablo® Hemodialysis System is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Treatments must be administered under physician's prescription and observed by a trained individual who is considered competent in the use of the device. The Tablo Hemodialysis System is also indicated for use in the home. Treatment types available include Intermittent Hemodialysis (IHD), Sustained Low Efficiency Dialysis (SLED/ SLEDD), Prolonged Intermittent Renal Replacement Therapy (PIRRT), and Isolated Ultrafiltration.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(21 CFR 807.92)

I. SUBMITTER

Name:	Outset Medical, Inc. 3052 Orchard Drive San Jose, CA 95134
Primary Contact:	Claire Bao Senior Regulatory Affairs Specialist Outset Medical, Inc. +1 (213) 610-3589
Date Prepared:	September 28, 2023

II. DEVICE

Trade/Proprietary Name:	Tablo® Hemodialysis System
Common /Generic Name:	Hemodialysis delivery system and water purification system
Classification Regulations:	21 CFR § 876.5860 – High permeability hemodialysis system 21 CFR § 876.5655 – Water purification system for hemodialysis
Product Codes:	KDI; FIP
Regulatory Class:	II

III. PREDICATE DEVICE

The predicate device to which substantial equivalence is claimed is:
Tablo Hemodialysis System, K223248

IV. INDICATION FOR USE

The Tablo Hemodialysis System is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Treatments must be administered under physician's prescription and observed by a trained individual who is considered competent in the use of the device. The Tablo Hemodialysis System is also indicated for use in the home. Treatment types available include Intermittent Hemodialysis (IHD), Sustained Low Efficiency Dialysis (SLED/ SLEDD), Prolonged Intermittent Renal Replacement Therapy (PIRRT), and Isolated Ultrafiltration.

V. DEVICE DESCRIPTION

The Tablo Hemodialysis System is a self-contained hemodialysis system intended for acute and chronic dialysis therapy, with or without ultrafiltration, in an acute, chronic care facility or in the home. The Tablo Hemodialysis System consist of:

1. Tablo Console
2. Tablo Cartridge

Figure 5-1 below provides an overview of the Tablo Hemodialysis System consisting of the Tablo Console and Cartridge.

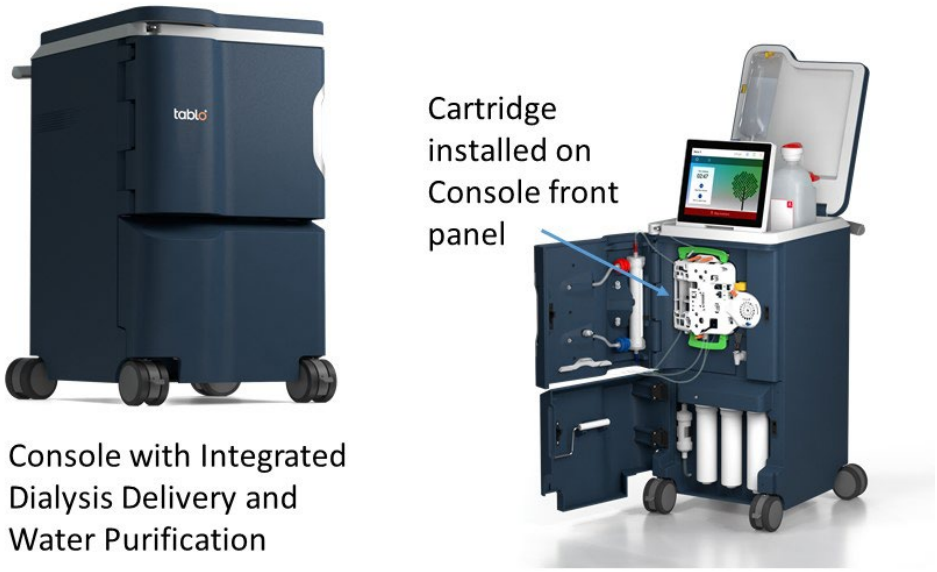

Figure 5-1: Tablo® Hemodialysis System with Cartridge Inserted

The Tablo Hemodialysis System with updated hydraulics does not affect the functionality of the Tablo cartridge, which was cleared under K190793 and K210782.

Accessories:

List of Accessories Supplied by Outset Medical:	**List of Dialysis Treatment Accessories Supplied by OEMs:**
• Straws • Patient Key • Outset Acid jug (Optional) • Outset Bicarbonate jug (Optional) • Non-invasive Blood Pressure Cuff (NIPB) kit, adult size medium. Small and large sizes are not shipped with the Console but can be ordered from Outset Medical. • Hand-Crank • Power Cord	• High Flux Dialyzer (prescription required) • Acid jug (If not using Outset Supplied Acid jug) • Bicarbonate jug (If not using Outset Supplied Acid jug) • Minncare HD or Minncare Cold Sterilant • Chlorine/Chloramine test kit • Saline bags • Heparin • Syringes and needles • Gloves and mask

• Drain Line • Water Line • Disinfectant Straws (Adapter)	• Biohazard container • Disinfectant, gauze pads, and tape for access site

VI. SUBSTANTIAL EQUIVALENCE

In accordance with the 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k) Outset Medical reached the conclusion that the Tablo Hemodialysis System with updated hydraulic material and the predicate device are substantially equivalent. No new issues of safety or effectiveness were raised by the changes to the hydraulics of Tablo Hemodialysis System.

Substantial Equivalence Section provides a comparison of the technological characteristics for the predicate and subject device. The comparison table also provides a discussion for why any differences between the predicate and subject device do not impact the safety and effectiveness of the device.

The completed verification and validation of the device supports the safety and effectiveness of the subject Tablo Hemodialysis System. The results demonstrate that the Tablo Hemodialysis System is substantially equivalent to the predicate, legally marketed device, cleared under K223248.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing
Biocompatibility testing for the modified Tablo Hemodialysis System 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"*, dated September 8, 2023. The following endpoints were evaluated to support the biological safety of the Tablo Hemodialysis System:

- Cytotoxicity
- Sensitization, Guinea Pig Maximization
- Intracutaneous Irritation
- Material-Mediated Pyrogenicity
- Hemocompatibility, ASTM Hemolysis (direct contact)
- Chemical Characterization
- Toxicological Risk Assessment

Electrical safety and electromagnetic compatibility (EMC)
The changes to the hydraulics do not impact the electrical safety or EMC of the Tablo Hemodialysis System. Therefore, no additional electrical safety or EMC testing was conducted to support the modified device.

Software Verification and Validation Testing

No software modifications were made as a result of the changes to the Tablo Console hydraulics. No new software verification and validation testing is required to support the change.

Sterilization and Shelf Life
Tablo Console is a reusable, non-sterile device. The components are disinfected using either heat disinfection or chemical disinfection using the pre-programmed machine disinfection cycle. Cleaning and disinfection methods are the same as predicate Tablo Hemodialysis System K223248 and have been described in device labeling and User manuals in Section 13 Labeling of this submission. No changes were made to the Table Cartridge within this submission.

Bench Performance Testing
The bench performance testing for the subject Tablo Hemodialysis System was conducted in accordance with FDA guidance document, "Guidance for the Content of Premarket Notifications for Hemodialysis Delivery System", dated August 7, 1998.

Following nonclinical bench performance tests were conducted to demonstrate that the modified Tablo Hemodialysis System meets the system requirements and performs as intended. The performance characterization of the subject device is the same as the predicate Tablo Hemodialysis System (cleared under K223248):

- Dialysate Temperature Accuracy
- Fluid Removal Accuracy
- Chemical Disinfection
- Heat Disinfection
- Related Alarms

Human Factors Validation Testing
The modifications to the hydraulics do not impact the usability of the Tablo Hemodialysis System. No new Human Factors validation study is deemed necessary to support the modifications to the material used in the hydraulics of the Tablo Hemodialysis System (Console).

Animal Study
No animal studies were conducted to support the modifications to the material used in the hydraulics of the Tablo Hemodialysis System (Console).

Clinical Studies
No clinical studies were conducted to support the modifications to the material used in the hydraulics of the Tablo Hemodialysis System (Console).

VIII. CONCLUSION

The Tablo Hemodialysis System's intended use including its indication for use, fundamental technological characteristics, performance specifications, principle of operation, functionality, intended patient population, anatomical location of use, user interface, clinical conditions and use environments have remained the same. The completed verification and validation of the device supports the safety and effectiveness of the subject Tablo Hemodialysis System. The results demonstrate that the Tablo

Hemodialysis System is substantially equivalent to the predicate, legally marketed device, cleared under K223248.