May 3, 2024

Outset Medical, Inc.
Joshua J. Mink
Senior Manager, Regulatory Affairs
3052 Orchard Drive
San Jose, CA 95134

Re: K232776
Trade/Device Name: Tablo® Hemodialysis System; TabloCart™ with Prefiltration Drawer
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI, FIP
Dated: April 29, 2024
Received: April 30, 2024

Dear Joshua J. Mink:

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

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232776

Device Name
Tablo® Hemodialysis System;
TabloCart™ with Prefiltration Drawer

Indications for Use *(Describe)*
The Tablo® Hemodialysis System and TabloCart™ 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.

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510(k) Summary

(21 CFR § 807.92)

I. SUBMITTER

Name: Outset Medical, Inc.
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Contact Details: Joshua Mink
Senior Manager, Regulatory Affairs
Outset Medical, Inc.
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Date Prepared: September 8, 2023

II. DEVICE

Trade/Proprietary Name: Tablo® Hemodialysis System
TabloCart™ with Prefiltration Drawer

Common /Generic Name: High Permeability Hemodialysis System

Classification Regulations: 21 CFR § 876.5860 – High permeability hemodialysis system
21 CFR § 876.5665 – Water purification system for hemodialysis

Product Codes: KDI; FIP

Regulatory Class: Class II

III. PREDICATE DEVICE

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

IV. MODIFICATION TO THE EXISTING DEVICE

Modifications described in this Traditional 510(k) do not add, delete, or modify the description of the currently marketed Tablo® Hemodialysis System[1], cleared under K223248. The system has been modified to include addition of an optional prefiltration cart without altering the system's intended use, indications for use, incoming water specifications or the fundamental scientific technology or principle of operation for the system.

The TabloCart™ with Prefiltration Drawer[2] is an optional accessory to the Tablo Hemodialysis System that raises the height of the system and includes larger wheels that rotate and lock in more functional directions than the system without cart, aiding in system mobility. When configured with a prefiltration drawer, the cart has replaceable, large-capacity cartridge filters (sediment and/or carbon) that serve as "prefilters" to help remove major sediment and chlorine/chloramines from supply water before it enters the Tablo Water Purification System. The cart with prefiltration also includes backflow prevention and a booster pump to help transport water from the incoming supply to the Tablo System.

[1] The Tablo® Hemodialysis System may be referenced synonymously throughout supporting documentation as "Tablo System" | "System" | "Console" | "Tablo X".

[2] The TabloCart™ with Prefiltration Drawer may be referenced synonymously throughout supporting documentation as "TabloCart" | "cart"| "accessory cart" | "Fluid Motion" | "prefiltration cart".

V. INDICATION FOR USE

There is no change to the intended use or indication for use for the subject device when compared to the predicate device cleared under K223248. The optional accessory cart has the same indications for use as the predicate device with the addition of "and TabloCart" to the statement, as listed below.

Indications for Use (Tablo Hemodialysis System, K223248):

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.

Indications for Use (TabloCart with Prefiltration Drawer):

The Tablo® Hemodialysis System and TabloCart 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.

Use, or non-use, of the TabloCart with Prefiltration Drawer has no impact to the Tablo Hemodialysis System's intended use or indications for use.

VI. INTENDED USE

There is no change to the intended use for the Tablo Console, cleared under K223248. Addition of the optional accessory cart does introduce a modified intended use specific to the cart, as listed below.

Intended Use (Tablo Hemodialysis System, K223248):

The intended use of the Tablo Hemodialysis System is for treatment of patients with end stage renal disease (ESRD) who require hemodialysis, with or without ultrafiltration, through a vascular access (i.e., fistula, graft, catheter).

Intended Use (TabloCart with Prefiltration Drawer):

The TabloCart with Prefiltration Drawer is intended to serve as an optional accessory to the Tablo Hemodialysis System, when increased height, improved mobility or additional, large capacity filters for sediment and/or chlorine/chloramine reduction are desired.

VII. 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 consists of:

- Tablo Console and Software
- Tablo Cartridge

The TabloCart™ is an optional accessory to the Tablo Hemodialysis System that raises the height of the Tablo console and includes larger wheels that rotate and lock in more functional directions than the Tablo console without a cart, aiding in overall system mobility. When configured with a Prefiltration Drawer, the cart has replaceable, large-capacity cartridge filters (sediment and/or carbon) that serve as "prefilters" to help remove major sediment and chlorine/chloramines from supply water before it enters the Tablo console's water purification system. The cart with prefiltration also includes backflow prevention and a booster pump to transport water from the incoming water supply to the Tablo console.

The TabloCart with Prefiltration Drawer consists of:

- Tablo Cart Wheeled Platform, Fluidics Drawer and Software

Figure 5-1 provides an overview of the Tablo Hemodialysis System mounted to the optional TabloCart with Prefiltration Drawer. The TabloCart is designed for compatibility with the Tablo Hemodialysis System only.

Figure 5-1: Tablo Hemodialysis System mounted to optional accessory, the TabloCart with Prefiltration Drawer

The Tablo Hemodialysis System is designed to operate as intended with or without use of the optional cart and the cart is compatible only with the Tablo Hemodialysis System. The proposed accessory cart does not affect the functionality of the Tablo Hemodialysis System, cleared under K223248.

Accessories supplied by Outset Medical is unchanged from those described in K223248 (See 11.1 Device Variant and Accessories) with the exception of the accessory TabloCart. The list of dialysis treatment accessories supplied by OEMs also remains unchanged from those identified in K223248.

VII. SUBSTANTIAL EQUIVALENCE

In accordance with *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k)*, Outset Medical, Inc. (Outset) has reached the conclusion that the Tablo Hemodialysis System and TabloCart with Prefiltration Drawer is substantially equivalent to the predicate Tablo Hemodialysis System (without accessory cart). The predicate device is legally marketed and the system with and without the TabloCart have the same intended use. No new issues of safety or effectiveness were raised by the minor differences in technological characteristics.

Section 12- Substantial Equivalence provides a detailed 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 or effectiveness of the device. A summary of this comparison is provided below in **Table 5.1**.

Completed verification and validation of the device supports the safety and effectiveness of the subject Tablo Hemodialysis System and TabloCart with Prefiltration Drawer. The results demonstrate that the Tablo console with optional cart is substantially equivalent to the predicate, legally marketed device, cleared under K223248.

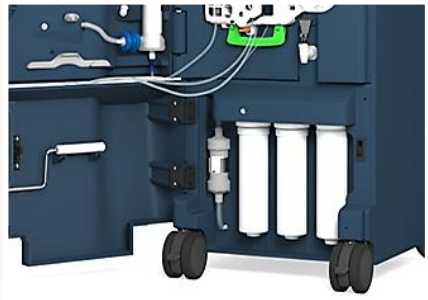
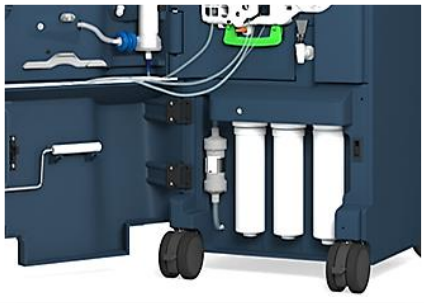
Table 5.1 Summarized Comparison Table

Parameter	Tablo Hemodialysis System (Predicate, K223248)	Tablo Hemodialysis System and TabloCart with Prefiltration Drawer (Subject Device)
Indications 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.	The Tablo® Hemodialysis System and TabloCart 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.
Class	II	II
Common Name	High Permeability Hemodialysis System	High Permeability Hemodialysis System
Product Code	KDI, FIP	KDI, FIP
Classification Panel	Gastroenterology / Urology	Gastroenterology / Urology
Regulation Number	21 CFR § 876.5860 High Permeability Hemodialysis System 21 CFR § 876.5665 Water Purification System for Hemodialysis	21 CFR § 876.5860 High Permeability Hemodialysis System 21 CFR § 876.5665 Water Purification System for Hemodialysis
Intended Use	The intended use of the Tablo Hemodialysis System is for treatment of patients with end stage renal disease (ESRD) who require hemodialysis, with or without ultrafiltration, through a vascular access (i.e., fistula, graft, catheter).	The intended use of the Tablo Hemodialysis System is for treatment of patients with end stage renal disease (ESRD) who require hemodialysis, with or without ultrafiltration, through a vascular access (i.e., fistula, graft, catheter). The TabloCart with Prefiltration is intended to serve as an optional accessory to the Tablo Hemodialysis System, when increased height, improved mobility or additional, large capacity filters for sediment and/or chlorine/chloramine reduction are desired.

Table 5.1 Summarized Comparison Table (Continued)

Parameter	Tablo Hemodialysis System (Predicate, K223248)	Tablo Hemodialysis System and TabloCart with Prefiltration Drawer (Subject Device)
Configuration Comparison	Tablo Hemodialysis System: Tablo Console Physical Dimensions: • Floor Space: 19 in. x 17.5 in. • System Height: 35.2 in. • Dry Weight: 195 lbs. Accessory Cart Physical Dimensions: N/A Mobility: • Four (4) rolling wheels ▪ Two (2) roll-locking wheels (front) and ▪ Two (2) 360° swiveling wheels (rear) Supply Water Filtration Console: • Two (2) carbon filters • One (1) sediment filter • One (1) Water Ultrafilter Accessory Cart with Prefiltration: N/A	Tablo Hemodialysis System mounted to optional TabloCart with Prefiltration Drawer (configured as 2S, 2C or SC): Tablo Console Physical Dimensions: • Floor Space: 19 in. x 17.5 in. • System Height: 35.2 in. • Dry Weight: 195 lbs. Accessory Cart Physical Dimensions: • Floor Space: 30 in. x 22.5 in. • Height: 11.1 in. • Dry Weight: 34 lbs. (15.42 kg) Mobility: • Four (4) 360° swiveling wheels ▪ Two (2) directional-locking and roll-locking wheels (front) and ▪ Two (2) directional locking (rear) Supply Water Filtration Console: • Two (2) carbon filters • One (1) sediment filter • One (1) Water Ultrafilter Accessory Cart with Prefiltration: • 2S: two (2) sediment filters or • 2C: two (2) carbon filters or • SC: one (1) sediment filter and one (1) carbon filter

Table 5.1 Summarized Comparison Table (Continued)

Parameter	Tablo Hemodialysis System (Predicate, K223248)	Tablo Hemodialysis System and TabloCart with Prefiltration Drawer (Subject Device)
Console Image		
Filtration, Volume	Tablo Hemodialysis System  Combined Carbon and Sediment Filter Volume: 15.8 cu. in.	Tablo Hemodialysis System and TabloCart with Prefiltration Drawer Combined Carbon and Sediment  +  Combined Carbon and Sediment Filter Volume: 103 cu. in.

VIII. PERFORMANCE DATA

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

Biocompatibility Testing
Comparative evaluation of the materials used for the Tablo Hemodialysis System and the TabloCart with Prefiltration Drawer are considered equivalent to the predicate Tablo Hemodialysis System cleared under K223248. Biocompatibility evidence is detailed in Section 15.

Electromagnetic Compatibility (EMC) and Electrical Safety
The subject device has no difference in the EMC and electrical safety from the predicate device, cleared in K223248. EMC and electrical safety evidence provided in K223248 included the Tablo Hemodialysis System and TabloCart with Prefiltration. Therefore, no additional electrical safety or EMC testing was conducted to support modified device. Current evidence is provided in Section 17 – Electromagnetic Compatibility and Electrical Safety.

Software Verification and Validation Testing
The software for the Tablo Hemodialysis System is not impacted by use, or non-use, of the TabloCart with Prefiltration. The cart is a water pre-filtration system for processing water before entry into the Tablo's water purification system, and its software functions independently from the Console. The software for the TabloCart with Prefiltration Drawer does not directly interact with the software installed on the Tablo Console. If any failure of the cart's software occurs, the cart will enter bypass mode, with operation of the Tablo Console uninterrupted.

Software verification and validation testing was conducted and passed at the system level for the Tablo Hemodialysis System connected to the optional TabloCart with Prefiltration Drawer accessory. The Documentation provided is per FDA's Guidance for Industry and FDA Staff: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, with the TabloCart software assessed as a Minor Level of Concern. Completed software testing, including evaluation of cybersecurity risks, supports that the safety and effectiveness of the system with optional cart is substantially equivalent to the predicate. Software evidence is detailed in Section 16.

Sterilization and Shelf Life (Cleaning, Disinfection)
The TabloCart with Prefiltration is a reusable, non-sterile accessory to the Tablo Hemodialysis System. Cleaning and disinfection methods for the optional cart are the same as for the predicate Tablo Hemodialysis System (K223248) and have been described in the device labeling, for Tablo Console and TabloCart Instructions for Use in Section 13 - Labeling.

Table Hemodialysis System (Console) labeling cleared under K223248 has not been modified by the addition of the TabloCart with Prefiltration Drawer, except for the addition of standalone labeling and instructions for use specific to the TabloCart.

Bench Performance Testing
Additional bench testing was conducted to support the accessory TabloCart with Prefiltration.
The performance characterization of the subject device is the same as the predicate Tablo Hemodialysis System (cleared under K223248).
No new Human Factors validation study was deemed necessary for the updated Tablo Hemodialysis System and TabloCart with Prefiltration Drawer.

Animal Study
No animal studies were conducted to support the Tablo Hemodialysis System and TabloCart.

Clinical Studies
No clinical studies were conducted to support the updated Tablo® Hemodialysis System and TabloCart with Prefiltration Drawer.

IX. CONCLUSION

The completed verification and validation of the device supports the safety and effectiveness of the subject Tablo® Hemodialysis System mounted atop the optional TabloCart™ with Prefiltration Drawer. The results demonstrate that the addition of the TabloCart™ with Prefiltration Drawer to the Tablo Hemodialysis System is substantially equivalent to the predicate, legally marketed device cleared under K223248.