January 26, 2026

Outset Medical, Inc.
c/o Dinamarie Stefani
Sr. Vice President, Quality Assurance &
Regulatory Affairs
3052 Orchard Drive
San Jose, CA 95134

Re: K253412
Trade/Device Name: Tablo® Hemodialysis System (PN-0008000, PN-0006000U)
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI FIP
Dated: December 23, 2025
Received: December 23, 2025

Dear Dinamarie Stefani:

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,

Gema Gonzalez -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253412

Please provide the device trade name(s).

Tablo Hemodialysis System (PN-0008000, PN-0006000U)

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

(21 CFR 807.92)

I. SUBMITTER

Name: Outset Medical, Inc.
3052 Orchard Drive
San Jose, CA 95134

Phone: +1-949-333-1222
Primary Contact: Dinamarie Stefani
Date Prepared: September 29, 2025

II. DEVICE

Trade/Proprietary Name: Tablo® Hemodialysis System (PN-0008000, PN-0006000U)

Common /Generic Name: Hemodialysis delivery system and water purification 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: II

III. PREDICATE DEVICE

The predicate device to which substantial equivalence is claimed is:
Tablo Hemodialysis System, K233335

IV. INDICATION FOR USE

The Tablo® Hemodialysis System and TabloCart™ are indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility, and/or in the home. Treatments must be administered under a physician's prescription and observed by a trained individual who is considered competent in the use of the device. 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 consists 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.

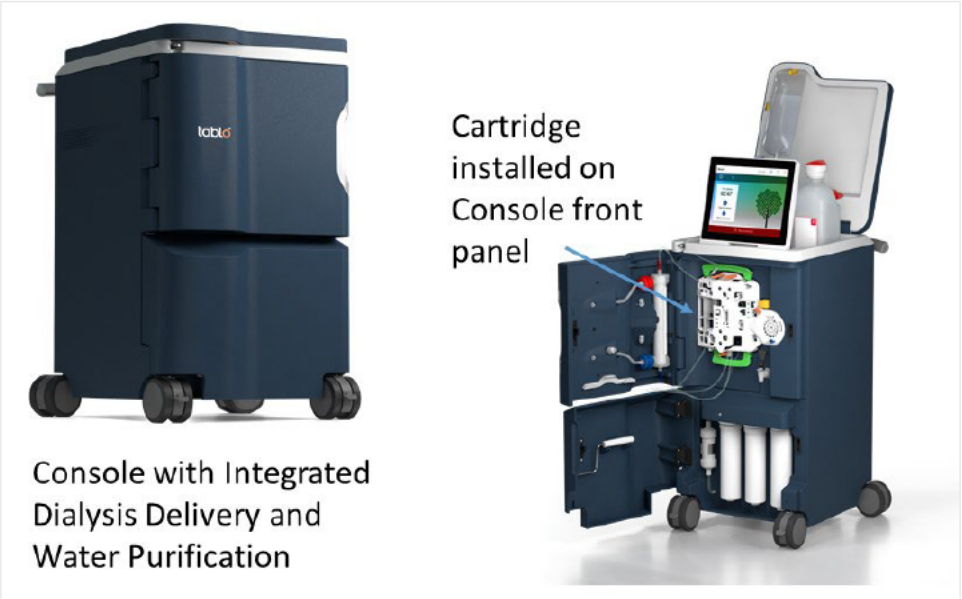

Figure 5-1: Tablo® Hemodialysis System with Cartridge Inserted

The proposed modifications for Tablo Hemodialysis System (Console) does not affect the functionality of the Tablo cartridge, which was cleared under K190793 and K210782.

The TabloCart with Prefiltration Drawer ("TabloCart") is an optional accessory to the Tablo Hemodialysis System that raises the height of the system, and features large, 360° rotating wheels to aid in system mobility. The Prefiltration Drawer features two replaceable cartridge filters (configurable with either two sediment (2S), two carbon (2C) or one sediment filter, and one carbon filter (SC)) that serve as "prefilters" to help remove sediment and/or chlorine/chloramines from supply water before it enters the Tablo's integrated water purification system.

The Tablo Hemodialysis System is designed to operate and achieve its intended use with or without use of the optional TabloCart. The TabloCart consists of TabloCart Wheeled Platform, Fluidics Drawer and Software. The Tablo Hemodialysis System uses its integrated water purification system, consisting of carbon, sediment, RO, and ultra-filters, to generate AAMI-quality water for dialysate fluid, even where the water is prefiltered using the TabloCart.

The proposed modifications for Tablo Hemodialysis System (Console) does not affect the functionality of the Tablo Cart, which was cleared under K232776.

Figure 5-2: Tablo® Hemodialysis System mounted to the TabloCart

Accessories:

List of Accessories Supplied by Outset Medical:	List of Dialysis Treatment Accessories Supplied by OEMs:

• Straws
• Patient Key
• Acid Concentrate (Optional)
• Bicarbonate Concentrate (Optional)
• Non-invasive Blood Pressure Cuff (NIPB) kit
• Blood pressure cuff patient hose with Suntech quick-connect fitting
• Hand-Crank
• Power Cord
• Drain Line
• Water Line
• Disinfectant Straws (Adapter)
• TabloCart
	• High Flux Dialyzer (prescription required)
	• Acid Concentrate (If not using Outset Supplied Acid Concentrate)
	• Bicarbonate Concentrate (If not using Outset Supplied Acid Concentrate)
	• Disposable non-invasive blood pressure cuff (Optional if not using Outset Medical supplied NIBP cuff)
	• Minncare HD or Minncare Cold Sterilant
	• Test strips for the presence of residual disinfectant. Use only qualified strips:
	  • Minncare HD Residual Test Strips
	  • Minncare Cold Sterilant Residual Test Strips
	  • RPC Micro-X® Peroxide/Peracetic Acid Residual Test Strips
	• Chlorine/Chloramine test kit
	• Saline bags
	• Heparin
	• Syringes and needles
	• Gloves and mask
	• Biohazard container
	• Disinfectant, gauze pads, and tape for access site
	• Blood leak test strips

VI. SUBSTANTIAL EQUIVALENCE

In accordance with FDA guidance document *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)],* Outset Medical reached the conclusion that the Tablo Hemodialysis System (Console) with software version 5.0 and the predicate device are substantially equivalent. The intended use is the same and no new questions of safety and effectiveness were raised by the minor differences in technological characteristics.

The Substantial Equivalence section of the submission 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 raise new questions of 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 (Console) with software version 5.0. The results demonstrate that the Tablo Hemodialysis System (Console) with software version 5.0 is substantially equivalent to the predicate, legally marketed device, cleared under K233335.

VII. PERFORMANCE DATA

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

Biocompatibility Testing
Materials and manufacturing/processing are identical to the predicate Tablo Hemodialysis System cleared under K233335. The proposed modifications are for components in the fluid pathway of Tablo Console. These components are assessed to be an auxiliary component[1] in the Tablo Console. Therefore, it does not impact the overall conclusion of biocompatibility per ISO 10993-1:2018 and previous testing conducted is applicable. Therefore, no additional biocompatibility data is deemed necessary for this submission.

Electrical Safety and Electromagnetic Compatibility (EMC)
The Tablo Hemodialysis System (Console) with software version 5.0 underwent all EMC tests required by IEC 60601-1-2 (Edition 4.1) equivalent to IEC 60601-1-2 (Edition 4.0) with Amendment 1:2020.

Software Verification and Validation Testing
Software verification and validation testing were conducted and passed for the subject device. 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"*. The applicable documentation level for the software for this device is "Enhanced", since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator. Completed software testing supports safety and effectiveness of the device. Software changes were made to strengthen the cybersecurity profile of the Tablo Console. Documentation provided is per FDA's Guidance for Industry and FDA Staff,

[1] According to the FDA's Guidance for the *Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis*, the term auxiliary component refers to a component which does not directly affect water quality, such as pumps, valves, tubing, pressure gauges, etc.

"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

Sterilization and Shelf Life
Tablo Console is a reusable, non-sterile device. Cleaning and disinfection methods for the Tablo Hemodialysis System (Console) with software version 5.0 are the same as the predicate Tablo Hemodialysis System (K233335) and have been described in device labeling and User manuals per the Labeling section. No changes were made to the Tablo Cartridge within this submission.

Bench Performance Testing
Bench testing was completed to support the incremental hardware changes to support reliability, serviceability and cost savings. The performance characterization of the subject device is the same as the predicate Tablo Hemodialysis System (K233335). No new Human Factors validation study was deemed necessary for the updated Tablo Hemodialysis System (Console) with software version 5.0.

Animal Study
No animal studies were conducted to support the updated Tablo Hemodialysis System (Console) with software version 5.0.

Clinical Studies
No clinical studies were conducted to support the updated Tablo Hemodialysis System (Console) with software version 5.0.

VIII. CONCLUSION

The indications for use, target patient population (acute/chronic renal failure), and use environments (clinical/home) are identical to the predicate, with minor wording revisions for clarity. The completed verification and validation of the device supports the safety and effectiveness of the subject Tablo Hemodialysis System (Console) with software version 5.0. The results demonstrate that the Tablo Hemodialysis System (Console) with software version 5.0 is substantially equivalent to the predicate, legally marketed device, cleared under K233335.