June 21, 2023

Outset Medical, Inc.
Saket Bhatt
VP, Global Regulatory Affairs
3052 Orchard Drive
San Jose, CA 95134

Re: K223248
Trade/Device Name: Tablo® Hemodialysis System
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI, FIP
Dated: May 19, 2023
Received: May 22, 2023

Dear Saket Bhatt:

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,

Gema Gonzalez -S

Gema Gonzales, MS
Acting 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)*

K223248

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.

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510(k) Summary

(21 CFR 807.92)

I. SUBMITTER

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

Phone: (330) 261-7717
Primary Contact: Keshu Nso
Date Prepared: June 21, 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 AND REFERENCE DEVICES

The predicate device to which substantial equivalence is claimed is:
Tablo Hemodialysis System, K211370

For Tablo specification change for intermittent therapy up to a maximum of 24 hours, Outset has identified two reference devices.

- NxStage System OneS, K133547
- Quanta SC+ Hemodialysis System, K222067

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.

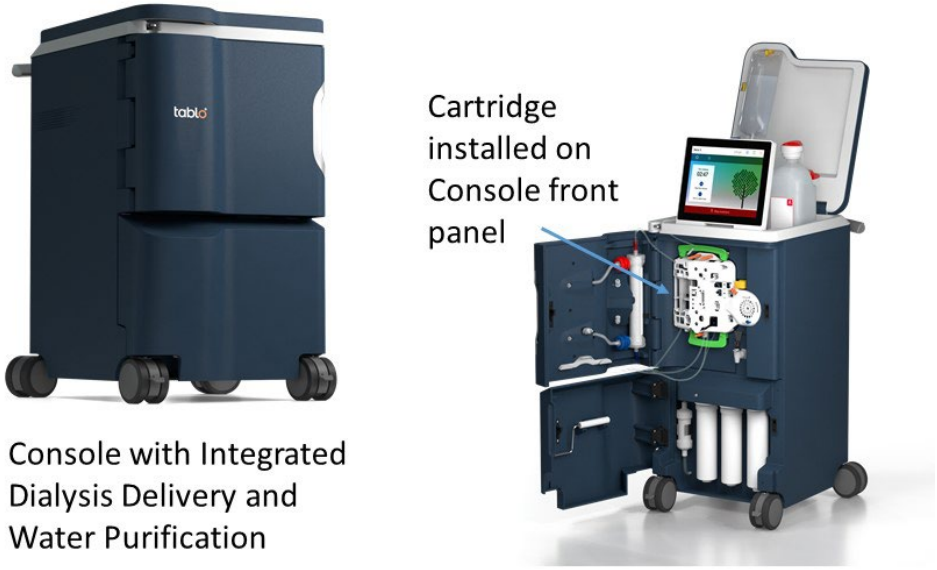

Figure 5-1: Tablo® Hemodialysis System with Cartridge Inserted

The proposed new software version for Tablo Hemodialysis System (Console) 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 • Drain Line • Water Line • Disinfectant Straws (Adapter)	• 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 • 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 new Tablo Hemodialysis System (Console) software version and the predicate device are substantially equivalent. No new issues of safety or effectiveness were raised by the minor differences in technological characteristics.

Section 12- Substantial Equivalence provides a comparison of the technological characteristics for the predicate, reference and subject device. The comparison table also provides a discussion for why any differences between the predicate, reference 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 K211370.

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 K211370. Therefore, no additional biocompatibility data is deemed necessary for this submission.

Electrical safety and electromagnetic compatibility (EMC)

The subject device has no difference in the EMC and electrical safety from the predicate device, cleared by FDA in K211370. Therefore, no additional EMC testing was conducted to support modified device.

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 software for this device is considered a "major" level of concern, 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.

Sterilization and Shelf Life
Tablo Console is a reusable, non-sterile device. Cleaning and disinfection methods are the same as predicate Tablo Hemodialysis System K211370 and have been described in device labeling and User manuals in Section 13 – Labeling. No changes were made to the Table Cartridge within this submission.

Bench Performance Testing
No additional bench testing was deemed necessary to support the new Tablo Hemodialysis System (Console) software version. The performance characterization of the subject device is the same as the predicate Tablo Hemodialysis System (cleared under K211370). Additional Human Factors validation data was provided for the updates made to the Tablo Hemodialysis System (Console) software version.

Performance testing conducted to demonstrate that the Tablo device can provide safe and effective treatment for a duration of up to 24 hours is presented. A summary of system-level testing, essential performance testing, alarms testing, software verification testing, mechanical hemolysis testing, and protective systems testing is presented.

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

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

VIII. CONCLUSION

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 K211370.