July 29, 2022

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

Re: K211370
Trade/Device Name: Tablo® Hemodialysis System (software version 4.8)
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: Class II
Product Code: KDI, FIP
Dated: July 29, 2022
Received: July 29, 2022

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 and Part 809); 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, 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)*
K211370

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.

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:	(408) 701-7319
Contact:	Saket Bhatt
Date Prepared:	July 29, 2022

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, K200741

Additionally, the following device is used as a reference device to support the device differences:
Tablo Hemodialysis System, K190793

IV. INDICATION FOR USE

The labeled indication for use statement is as follows:

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.

V. CONTRAINDICATIONS

Prescribing physicians should consider the following contraindications for hemodialysis: very low blood pressure, shock, active, uncontrollable bleeding condition, or lack of vascular access. The passing of a patient's blood through an extracorporeal circuit may require anticoagulation to prevent blood clotting. In addition, the parameters of dialysis should be optimized to avoid discomfort to the patient.

The use of third-party external infusion pump is contraindicated with the Tablo System for home users for all fluid infusions including heparin infusion.

VI. 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 or chronic care facility or in the home. The device includes the:

- Tablo Console, a single module consisting of multiple fluidic systems that perform the activities of a water purification system (WPS) and a conventional dialysis delivery system (DDS), and
- Table Cartridge

The following are accessories available from Outset:

- Tablo Straws
- Patient Key (USB)
- Outset Acid Concentrate 1K, 2K and 3K (Optional)
- Outset Bicarbonate Concentrate jug (Optional)
- Non-invasive Blood Pressure Cuff (NIPB) kit
- Hand-Crank
- Locking Power Cord
- Drain Line
- Water Line
- Insert and straw for Minncare Cold Sterilant
- Tablo Script

Field Replaceable Units:

- Filter, Chlorine/Chloramines (Carbon Filter)
- Filter, Sediment
- Filter, RO Membrane
- Ultrafilter (Water and Dialysate Ultrafilter)

The following are dialysis treatment recommended accessories which are commercially available by other manufacturers:

- High Flux Dialyzer
- Acid jug (If not using Outset Supplied Acid Concentrates jug)
- Bicarbonate jug (If not using Outset Supplied Bicarbonate jug)
- Minncare Cold Sterilant
- Chlorine/Chloramine test kit
- Saline bag

- Syringes and needles
- Gloves and mask
- Biohazard container
- Disinfectant, gauze pads, and tape for access site

VII. SUBSTANTIAL EQUIVALENCE

The modified Tablo Hemodialysis System has the same fundamental technology, principle of operation, and principle functionality as the predicate. The device is a high permeability hemodialysis system, which combines a water purification system and dialysate delivery system as one device system.

The following differences exist between the predicate and subject device:

- Hardware changes: these features are the same as those in the cleared reference device,
- Software changes: these changes align the subject device software to that of the cleared reference device,
- Updated software to restrict functionality by use settings (professional and self-care mode).

VIII. PERFORMANCE DATA

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

Biocompatibility Testing
In accordance with the FDA *Guidance for the Content of Premarket Notifications for Hemodialysis Delivery Systems*, issued August 7, 1998, Section VII, C, Outset Medical followed the alternative path and conducted leachable testing in lieu of biocompatibility tests. Toxicological assessment was performed. Device materials are considered safe for use as intended.

Electrical safety and electromagnetic compatibility (EMC)
The device was tested against and complies with ES 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11, and IEC 60601-2-16. RFID testing per AIM 7351731 was also conducted.

Software Verification and Validation Testing
Software verification and validation testing were conducted and passed for the incremental software changes. 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
N/A, Tablo Console is reusable, non-sterile. No changes were made to the Table Cartridge within this submission.

Bench Performance Testing

Bench testing to support the updated Tablo Console is as described in the reference device 510(k) K190793 and additional testing was conducted as described below:

Test Performed	Acceptance Criteria	Result
Fungistasis and Bacteriostasis	The system shall not inhibit detection and/or the recovery of potential organisms as per USP 61.	Pass
Reprocessing Disinfection Validation	The system shall be labeled with cleaning instructions in accordance with FDA guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" dated March 2015.	Pass
Human Factors Validation	The system shall be assessed for usability with representative home users in accordance with its intended use/indication for use. The FDA guidance document used is "Applying Human Factors and Usability Engineering to Medical Devices" dated February 2016.	Pass

Animal Study
No animal studies were conducted to support the modified device.

Clinical Studies
No clinical studies were conducted to support the modified device.

IX. CONCLUSION

Non-clinical testing supports the safety and effectiveness of the Tablo Hemodialysis System. The results from these tests demonstrate that the device system performs comparably to the predicate device and is substantially equivalent to the legally marketed device, K200741.