March 31, 2020

Outset Medical, Inc.
Jennifer Mascioli-Tudor
Vice President of Quality Assurance and Regulatory Affairs
1830 Bering Drive
San Jose, CA 95112

Re: K200741
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: March 20, 2020
Received: March 24, 2020

Dear Jennifer Mascioli-Tudor:

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,

Carolyn Y. Neuland, Ph.D.
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K200741

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.

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

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# 510(k) Summary

## I. SUBMITTER

Name: Outset Medical, Inc.
1830 Bering Drive
San Jose, CA 95112

Phone: (669) 231-8200
Primary Contact: Jennifer Mascioli-Tudor
Secondary Contact: Mara Marshak
Date Prepared: March 20, 2020

## II. DEVICE

Name of Device: Tablo® Hemodialysis System

Common or Usual Name:
Hemodialysis delivery system and water purification system

Classification Name:
High Permeability Hemodialysis System (21 CFR § 876.5860) Product Code: KDI
Water Purification System for Hemodialysis – Product Code: FIP

Regulatory Class: II

## III. PREDICATE DEVICE

Tablo Console, K160881
The predicate device has not been subject to a design related recall.
No reference devices were used in this submission.

## IV. 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. This premarket notification is an indication expansion to include home use of the device. The product described in this submission includes:

- 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
- The following accessories/components
    - Tablo Script (optional accessory software)
    - Tablo Straws
    - Outset Acid Concentrate 1K, 2K and 3K
    - Outset Bicarbonate Concentrate
    - Patient USB Stick

- Hand Crank
- Locking Power Cord
- Drain Line
- Water Line
- Disinfectant Straw

## V. INDICATIONS FOR USE

The indications for use statement was modified to include home 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.*

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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 technological differences exist between the predicate and subject devices:

- Added Outset 1K acid concentrate
- Venous drip chamber level sensor change
- 1-way data transmission from the device to the cloud for home users
- Software reliability improvements

## VII. PERFORMANCE DATA

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

**Biocompatibility Testing**
No additional testing was conducted to support the modified device.

**Electrical safety and electromagnetic compatibility (EMC)**
Complies with ES 60601-1, IEC 60601-1-2, IEC 60601-1-8, IEC 60601-1-10, IEC 60601-1-11, and IEC 60601-2-16. RFID testing per AIM 7351731.

**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.

**Bench Performance Testing**
The following test were completed to support the subject device.

| Test Performed | Acceptance Criteria | Result |
|---|---|---|
| AAMI Water and AAMI Dialysate Quality Verification | The system shall meet ANSI/AAMI 13959:2014 and ANSI/AAMI 11663:2014 requirements for water and dialysate under worst case input test conditions. | Pass |
| 1K Concentrate Compatibility Verification | The system shall be compatible with the Outset branded 1K acid concentrate | Pass |
| Drip Chamber Level Sensor Verification | The modified sensors shall meet pre-specified functional and performance requirements. | Pass |
| Suitability Test – USP<61> Microbial Enumeration Test | The system shall not inhibit detection and/or the recovery of potential organisms. | 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,* issued March 17, 2015. | Pass |

**Human Factors**
Human factors validation conducted in accordance with the FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices", issued February 3, 2016.

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

**Clinical Studies**
Outset Medical conducted the Tablo clinical study, a prospective, multicenter, open label, non-randomized, cross-over study evaluating the use of the Tablo Hemodialysis System In-Center and In-Home by trained subjects with end stage renal disease (ESRD) who are on stable dialysis regimen. Use of the Tablo Hemodialysis System is associated with a low adverse event rate and can safely be used at home by ESRD patients. The recommended adequacy target of home hemodialysis (a weekly standardized Kt/V of 2.1) can consistently and effectively be delivered with the Tablo Hemodialysis System when used by End Stage Renal Disease patients in the home environment. Additionally, patients reliably achieve ultrafiltration goals using the System at home. The Tablo Hemodialysis System is safe and effective for home use.

## VIII. CONCLUSION

The clinical and non-clinical data support that the modified Tablo Hemodialysis System, when used in the home environment, is as safe and effective and therefore, is substantially equivalent to the predicate device, K160881.