



December 12, 2019

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

Re: K190793
Trade/Device Name: Tablo® Hemodialysis System
Tablo® Cartridge
Regulation Number: 21 CFR 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI, FIP, FJK
Dated: April 16, 2019
Received: April 18, 2019

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

Indications for Use

510(k) Number (if known)

K190793

Device Name

Tablo® Hemodialysis System, Tablo® Cartridge

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, with a trained individual available as needed who is considered competent in the use of the device by the prescribing physician.

The Tablo® Cartridge is a single use, disposable arterial and venous bloodline set intended to provide extra-corporeal access during hemodialysis. The Tablo Cartridge is compatible only with the Tablo Hemodialysis System.

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

I. SUBMITTER

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: November 8, 2019

II. DEVICE

Name of Device:
Tablo® Hemodialysis System;
Tablo® Cartridge

Common or Usual Name:
Hemodialysis delivery system and water purification system; Blood tubing set

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

Regulatory Class: II

III. PREDICATE DEVICE

Tablo Console, K160881;
Tablo Cartridge, K140841

These predicates have 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. The system's innovative design 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
- Tablo Cartridge, a single use blood tubing set attached to an organizer tray. The ethylene oxide (EO) sterilized and disposable cartridge is inserted onto the front panel of the console for each dialysis treatment (**Figure 1**).
- Tablo Script, an accessory software to the Tablo Console, is designed for use by medical professionals to a) prepare, update and verify patient dialysis prescriptions b) view and export dialysis treatment information and billing activities and c) set and modify Tablo Console settings. Note: Tablo Script is optional, patient prescriptions can still be created or changed directly on the Tablo Console.

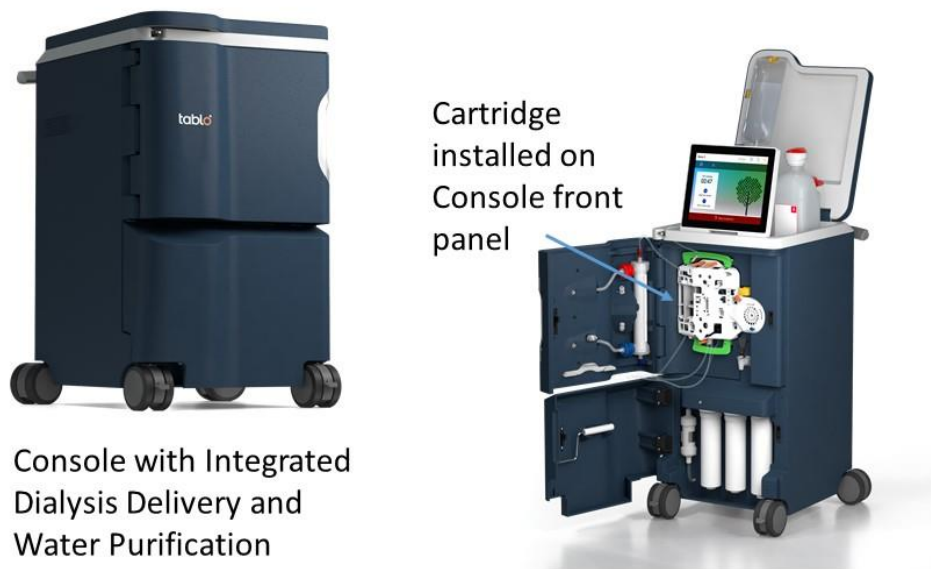


Figure 1: Tablo Hemodialysis System with Cartridge Inserted

The following are accessories supplied by Outset for use with Tablo:

- Tablo Straws
- Patient Key (USB)
- Outset Acid Concentrate 1K, 2K and 3K (Optional)
- Outset Bicarbonate Concentrate (Optional)
- Non-invasive Blood Pressure Cuff (NIPB) kit
- Hand-Crank

- Locking Power Cord
- Drain Line
- Water Line
- Insert and straws for Minncare Cold Sterilant

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 jug)
- Bicarbonate jug (If not using Outset Supplied Bicarbonate jug)
- 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

V. INDICATIONS FOR USE

The identical indications for use statement, except for registered trademarks and clarified tradename, are 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, with a trained individual available as needed who is considered competent in the use of the device by the prescribing physician.

The Tablo® Cartridge is a single use, disposable arterial and venous bloodline set intended to provide extra-corporeal access during hemodialysis. The Tablo Cartridge is compatible only with the Tablo Hemodialysis System.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified Tablo Hemodialysis System and Tablo Cartridge have the same fundamental technology, principle of operation, and principle functionality. The device is a high permeability hemodialysis system, which uses the same principle of reverse osmosis as its water purification system combined into one preconfigured integrated machine. The Tablo Cartridge is intended as the hemodialysis blood tubing set and has the same compatibility only with Tablo.

The subject and predicate devices are based on the following same technological elements:

- essential performance per IEC 60601-2-16
- internal water purification system
- dialysate delivery system

The following technological differences were described for the proposed device:

- Tablo Console Front Panel
 - Tablo Peristaltic Venous Air Pump (VAP)
 - Tablo Active Conductivity
 - Tablo Heaters and Thermal Management
 - Tablo 60601-2-16 Sensor Changes
 - Tablo Maintenance of AAMI Quality Water and Dialysate
 - Tablo Thermistors
 - Tablo Electrical Architecture
 - Tablo Diener Pumps
 - Tablo Ultrafiltration Accuracy
 - Tablo Chemical and Heat Validation
 - Cartridge Pouch as Prime Discard Receptacle
 - Y Connector that attaches Arterial and Venous Lines together
 - Minor Molded Organizer Tray Changes
 - Heparin Pump Removal and Infusion Line Minor ID Increase
 - Tube Coiling and Length Increase
 - Needleless Infusion Port Design
 - Shelf Life to 12 months
 - Maximum Operating Pressure roll-up from Console
 - Labeled Priming Volume
 - Compatibility with Commercial Accessories
 - Soft Power Switch
 - Specification update for Treatment Time
 - Allow the use of Non-Outset Branded Concentrates
 - Allow entering patient prescription data directly on the console
 - Improve reliability of wireless data transmission
-

VII. PERFORMANCE DATA

The following performance data were provided to support substantial equivalence of the device.

Biocompatibility testing

For the Tablo Cartridge, biocompatibility evaluation was conducted in accordance with the FDA guidance document, *Hemodialysis Blood Tubing Sets - Premarket Notification [510(k)] Submissions*, dated April 23, 2008. The battery of tests include the following tests for externally communicating devices, contacting circulating blood, prolonged contact Class II (Category B):

- Cytotoxicity
- Sensitization
- Intracutaneous reactivity
- Acute systemic toxicity
- Hemocompatibility
- Genotoxicity

Results were passing under the conditions of the individual tests.

For the fluid contact materials of the Tablo Console, 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 and device materials are considered safe for use as intended.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Tablo Hemodialysis System, consisting of the blood tubing set cartridge and Tablo console. The system complies with the ES 60601-1, main and its collateral standards.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by 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 was considered as 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.

Shelf Life and Sterilization Testing (Tablo Cartridge)

Test	Acceptance Criteria	Result
Device Performance	Device meets performance requirements following 1 year accelerated aging	Pass
Packaging integrity	Packaging system meets performance requirements following 1 year accelerated aging.	Pass
Sterilization	Device is EO sterilized, meets SAL of 10^{-6}	Pass
EO residuals	Meets ISO 10993-7 for prolonged contact device	Pass
Bacterial endotoxin (LAL) testing	Meets ANSI/AAMI ST72	Pass

Bench Performance Testing

Test Performed	Acceptance Criteria	Result
1. Environmental Operation	The device shall meet the system requirements for environmental operation.	Pass
2. Transit	The system shall operate within specification after transit.	Pass
3. Prime Discard	The Tablo Cartridge shall meet the requirements for prime discard.	Pass
4. Pinch Valve	The system shall meet requirements for the blood and saline pinch valves.	Pass
5. Maximum Power	The system shall meet requirements for maximum power and current.	Pass
6. Dialyzer Compatibility	The system shall be compatible with hemodialyzers of sizes with the following ranges: Major Diameter: 2.14 - 2.75" Minor Diameter: 1.45 - 2.05" Total Length: 11.55 - 13.15" Dialysate Port Distance: 8.15 - 9.55"	Pass
7. External Device Compatibility	The system shall be compatible with external devices (i.e., external infusion pump, manual syringe injection of saline bolus and Transonic sensors (Transonic part number H4FX).	Pass
8. Cartridge Hemolysis Testing, 12 Hours	The increase in hemolysis in a sample of blood circulating through the fluidic path during treatment as compared to a control sample of blood idle for the same amount of time shall not exceed 1%. The system shall meet its hemolysis requirements with a Crit-Line blood chamber (Fresenius part number 191058) connected within the extracorporeal circuit.	Pass
9. Various hardware	The system shall meet the following requirements for various hardware.	Pass
10. Water Ingress (IP21)	The console enclosure shall have an IP21 ingress protection rating per IEC 60529.	Pass
11. Mechanical	The system shall meet requirements for labeled priming volume, be designed with an ultrafilter that removes microbial materials and particles > 5nm, shall be designed with the required ports so that sampling for monitoring can be taken.	Pass
12. Front Panel Interface with Cartridge Installed	The system shall meet the following requirements for front panel interface with the cartridge installed.	Pass
13. Essential Performance per IEC 60601-2-16	The system shall meet Essential Performance per IEC 60601-2-16.	Pass

Bench Performance Testing

Test Performed	Acceptance Criteria	Result
14. Battery Failure	The system shall prevent treatment initiation if it detects a low battery voltage.	Pass
15. AAMI Water and Dialysate Quality	The system shall meet ANSI/AAMI 13959:2014 and ANSI/AAMI 11663:2014 requirements for water and dialysate.	Pass
16. Total Dissolved Solids	The system shall meet the requirements for total dissolved solids: - Water sample results meet ANSI/AAMI 13959 toxic contaminant standards and ISO 23500 trace element standards - Water from the Post RO sample port meets ISO 23500 electrolyte concentration limits when prepared from water with hardness of 150 mg/L	Pass
17. Water Treatment System	The system shall meet requirements for a water treatment system.	Pass
18. Dialysate flow and Conductivity Monitoring	The system shall meet requirements for dialysate flow, temperature, volume, and conductivity monitoring.	Pass
19. Air-In-Line	The system shall meet requirements related to the system's purging and detection of air bubbles in the extracorporeal circuit.	Pass
20. Pre-Treatment Mode	The system shall meet requirements for pre-treatment mode.	Pass
21. Post-Treatment Mode	The system shall meet requirements for post-treatment mode.	Pass
22. Blood Pump and Pinch Valve Control, and Saline Delivery Performance	The system shall meet requirements for operation, performance, and control of the peristaltic blood pump.	Pass
23. Heat Disinfection Mode	The system shall meet requirements for heat disinfection mode.	Pass
24. Chemical Disinfection Mode	The system shall meet requirements for chemical disinfection mode.	Pass
25. Ultrafiltration Accuracy	The system shall provide a treatment fluid removal accuracy of +/- 100 mL per hour of the treatment time.	Pass

Bench Performance Testing

Test Performed	Acceptance Criteria	Result										
26. Maintenance and Service User	The system shall meet requirements for maintenance and service user.	Pass										
27. Maintenance and Service User	The system shall allow the user to run mock treatments in Service Interface without the need of a Patient USB (a patient-specific secured USB storage device that contains encrypted treatment and prescription details).	Pass										
28. Heat and Chemical Disinfection Effectiveness	Disinfection validation was performed on n=3 consoles per organism, totaling n=6 consoles to demonstrate that chemical and heat disinfection cycles reduce vegetative bacterial species (i.e., <i>Pseudomonas aeruginosa</i>) by six logs and non-tuberculous Mycobacterium species (i.e., <i>Mycobacterium terrae</i>) by three logs.	Pass										
29. External Disinfectant Chemical Compatibility Testing (IEC 60601-2-16 Test)	<p>The system and its accessories shall be capable of withstanding daily cleaning, using the chemicals below, over the service life of the device per the chemical manufacturer instructions, with:</p> <ul style="list-style-type: none"> - 70% Isopropyl Alcohol - 10% bleach (0.3% - 0.6 % hypochlorite) - PDI Super Sani Cloth Germicidal Wipes - CaviWipes - CaviWipes1 Disinfecting Wipe - Oxivir 5 - Oxivir TB Wipes 	Pass										
30. Bring Your Own Concentrate Conductivity Test	<p>The system shall be compatible with dialysis fluid concentrates intended for a 45X-proportioning ratio. When mixed at a 45X ratio, the acid concentrate should comply with the following labeled formulation range:</p> <table border="1" data-bbox="467 1255 896 1402"> <thead> <tr> <th>Parameter</th> <th>Formulation</th> </tr> </thead> <tbody> <tr> <td>Sodium</td> <td>100 mEq/L</td> </tr> <tr> <td>Potassium</td> <td>0 – 4 mEq/L</td> </tr> <tr> <td>Calcium</td> <td>0 – 3.5 mEq/L</td> </tr> <tr> <td>Acetate</td> <td>4 mEq/L</td> </tr> </tbody> </table>	Parameter	Formulation	Sodium	100 mEq/L	Potassium	0 – 4 mEq/L	Calcium	0 – 3.5 mEq/L	Acetate	4 mEq/L	Pass
Parameter	Formulation											
Sodium	100 mEq/L											
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Acetate	4 mEq/L											
31. Human Factors Validation	The system shall be assessed for usability with representative users (i.e., nurses and patient care technicians in clinical settings and acute-care facilities) in accordance with its intended use/indications for use.	Pass										

Animal Study

No animal studies were performed in support of the modifications.

Clinical Studies

No clinical studies were performed in support of the modifications.

VIII. CONCLUSIONS

Non-clinical testing supports the safety and effectiveness of the Tablo Hemodialysis System and Tablo Cartridge. The bench testing demonstrates that the device system performs comparably to the predicate device and is substantially equivalent to the legally marketed device.
