November 15, 2016

Outset Medical, Inc.
Julie Newsome
Vice President of Quality
and Regulatory Operations
1830 Bering Drive
San Jose, CA 95112

Re: K160881
Trade/Device Name: Tablo Console
Regulation Number: 21 CFR§ 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI, FIP
Dated: October 13, 2016
Received: October 14, 2016

Dear Julie Newsome:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number *(if known)*
K160881

Device Name
Tablo Console

Indications for Use *(Describe)*
The Tablo™ 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.

Type of Use *(Select one or both, as applicable)*
- [x] 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.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASstaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
K160881 - 510(k) Summary

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR Part 807.92.

Submitter’s Information

<table>
<thead>
<tr>
<th>Field</th>
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<tbody>
<tr>
<td>Submitter’s Name:</td>
<td>Julie Newsome</td>
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<tr>
<td>Company:</td>
<td>Vice President, Quality and Regulatory Operations</td>
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<td>Address:</td>
<td>Outset Medical, Inc.</td>
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<td>1830 Bering Drive, San Jose, CA 95112</td>
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<td>Contact Person:</td>
<td>Julie Newsome</td>
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<td>Vice President, Quality and Regulatory Operations</td>
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<td>Date of Summary Preparation:</td>
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Device Information

<table>
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<tr>
<th>Field</th>
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<tr>
<td>Trade Name:</td>
<td>Tablo™ Console</td>
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<tr>
<td>Common Name:</td>
<td>Hemodialysis Delivery System</td>
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<td></td>
<td>Portable Water Treatment System</td>
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<td>Water Purification System for Hemodialysis</td>
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Predicate Device Information

The Tablo Console was originally cleared under K140866 and most recently cleared under K150880 for the addition of one-way Wireless Capability.

Device Description

The Tablo™ Console is a self-contained hemodialysis system (Console) intended for acute and chronic dialysis therapy with or without ultrafiltration, in an acute or chronic care facility. The console consists of fluidic systems that perform the activities of a Water Purification System (WPS) and a conventional Dialysis Delivery System (DDS). Since the original 510(k) clearance, the Tablo Console has incorporated design and corresponding labeling updates whose purpose was
to improve ease of manufacturing, increase reliability, simplify the design, and optimize performance.

**Indications for Use**
The Tablo 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.

**Key Performance Specifications/Characteristics of the Device**
The proposed Tablo Console with Expanded Wireless Data Transmission Capability and the predicate device (K150880) are equivalent in technological characteristics:

- Design and Construction
- Water Purification Method
- Dialysate Preparation
- Disinfection - Heat and chemical disinfection
- Materials (patient and non-patient contacting)
- Electrical safety and associated testing
- Compatibility – Interface with the Tablo Cartridge (Blood Tubing Set)
- Off the shelf components - Dialyzers and non-invasive blood pressure cuffs (NIBP).
- Standards - Electrical and electromagnetic safety, Water Purification, and Hemodialysis System standards.
- Software - Software controlled, and utilizes Graphic User Interface (GUI)
- Software – verification and validation
- Wireless data transmission capability

The principal purpose of this 510(k) is to describe the expanded wireless communication capabilities for the Tablo Console. The changes made to the device since the last 510(k) clearance K150880 are also covered within this 510(k) submission.
Comparison of Technological Characteristics with the Predicate Device
Performance testing completed on the proposed device to support the determination of substantial equivalence is summarized below and has been developed in accordance with appropriate FDA guidance documents and relevant standards.

Since the original clearance, the Tablo Console has incorporated design and corresponding labeling updates whose purpose was to improve ease of manufacturing, increase reliability, simplify the design, and optimize performance. The complete list of changes implemented and included in the Tablo Console Roll-Up attachment are included in the summary of performance data below.

Biocompatibility Testing
Design updates to the fluidic system have been made to the modified device and biocompatibility has been evaluated. There were no changes to the material type, formulation, chemical composition, material processing or contact duration. No additional testing was required.

Electrical Safety and Electromagnetic Compatibility (EMC)
The Tablo Console with Wireless Capability has been evaluated against the requirements for Electromagnetic Compatibility and Electrical Safety. The evaluation of the device was conducted in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, and IEC 60601-2-16.

Software Verification and Validation Testing
For all software modifications, system level software verification testing demonstrated that the Tablo meets functional and performance software requirements.

System Performance Testing
System Performance Testing included verification of design updates specific to the roll-up changes in the following areas:

- Fluidic System Optimization
- Front Panel Interface
- Console External and Internal Design
- System Accessories
- Dialyzer Prime
- Heat Disinfection

Animal Studies
No animal studies were performed in support of the modifications.

Clinical Studies
No clinical studies were performed in support of the modifications.
**Conclusion**

The performance testing demonstrates that the Tablo Console with expanded wireless capability meets all performance specifications and complies with applicable standards and FDA Guidance Documents. The proposed Tablo Console with expanded Wireless Capability is substantially equivalent to the predicate device, and the minor differences in the technological characteristics of the proposed and the predicate devices do not raise any new or different questions of safety or effectiveness.