



Food and Drug Administration  
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May 1, 2015

Outset Medical  
Nancy Gallo  
Sr. Vice President, Regulatory Affairs  
and Quality Assurance  
1830 Bering Drive  
San Jose, CA 95112

Re: K150880  
Trade/Device Name: Tablo Console  
Regulation Number: 21 CFR§ 876.5860  
Regulation Name: High permeability hemodialysis system  
Regulatory Class: II  
Product Code: KDI  
Dated: March 31, 2015  
Received: April 1, 2015

Dear Nancy Gallo,

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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)

K150880

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)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

## 7 510(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.

### 7.1 Submitter's Information

Submitter's Name:	Nancy Gallo
Company:	Outset Medical
Address:	1830 Bering Drive San Jose, CA 95112
Contact Person:	Nancy Gallo Sr. Vice President, Regulatory Affairs and Quality Assurance
Phone:	510.682.6505
Facsimile:	669.231.8201
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Date of Summary Preparation:	March 31, 2015

### 7.2 Device Information

Trade Name:	Tablo™ Console	
Common Name:	Hemodialysis Delivery System	Portable Water Treatment System
Classification Name:	High Permeability Hemodialysis Delivery System	Water Purification System for Hemodialysis
Classification Number:	Class II per 21 CFR 876.5860	Class II per 21 CFR 876.5665
Product Code:	KDI	FIP
Classification Panel:	Gastroenterology/Urology	Gastroenterology/Urology

### 7.3 Predicate Device Information

Tablo™ Console (K140866)

### 7.4 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).

### 7.5 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.

### 7.6 Technological Characteristics

The Tablo Console (Modified Device) and the Predicate Device are equivalent in technological characteristics:

- Intended use - To deliver hemodialysis to patients with renal disease.
- 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).
- Design and Construction
- Water Purification Method
- Dialysate Preparation
- Disinfection - Heat and chemical disinfection.
- Compatibility – Interface with the Tablo Cartridge (Blood Tubing Set)
- System Level Specifications

There is one difference between the Modified and Predicate Devices. The difference is limited to the inclusion of one-way wireless data transmission capability for medical informatics.

### 7.7 Performance Data

The following performance testing, developed in accordance with appropriate FDA guidance documents and relevant standards, has been performed on the Modified Device to support the determination of substantial equivalence:

- Performance testing to verify wireless compatibility of the system with other communication devices
- Performance testing to verify maintenance of the Electrical Safety and Electromagnetic Compatibility profiles
- Software verification

### 7.8 Conclusion

The performance testing demonstrates that the Tablo Console meets all performance specifications and complies with applicable standards and FDA Guidance Documents. The Tablo Console (Modified Device) is substantially equivalent to the Predicate Device, and the minor difference in the technological characteristics of the Modified and the Predicate Device does not raise any new or different questions of safety or effectiveness.