



November 26, 2021

Outset Medical, Inc.  
Claire Bao  
Sr. Regulatory Affairs Specialist  
3052 Orchard Drive  
San Jose, California 95134

Re: K210782  
Trade/Device Name: Tablo® Cartridge  
Regulation Number: 21 CFR 876.5820  
Regulation Name: Hemodialysis system and accessories  
Regulatory Class: II  
Product Code: FJK  
Dated: October 27, 2021  
Received: October 28, 2021

Dear Claire Bao:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Glenn B. Bell, Ph.D.  
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)  
K210782

Device Name  
Tablo Cartridge

Indications for Use (Describe)

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

(21 CFR 807.92)

### I. SUBMITTER

Name: Outset Medical, Inc.  
3052 Orchard Drive  
San Jose, CA 95134

Phone: (669) 231-8200

Primary Contact: Jennifer Mascioli-Tudor

Prepared by: Claire Bao

Date Prepared: March 24, 2021

### II. DEVICE

Trade/Device Name: Tablo Cartridge

Common or Usual Name: Blood tubing set

Regulation Name: Hemodialysis system and accessories

Regulation Number: 21 CFR § 876.5820

Product Code: FJK

Regulatory Class: II

### III. PREDICATE DEVICE

Tablo Cartridge (K190793)  
The predicate device has not been subjected to a design related recall.  
No reference devices were used in this submission.

### IV. DEVICE DESCRIPTION

The Tablo Cartridge is a single use blood tubing set attached to an organizer tray. The E-beam sterilized and disposable cartridge is inserted onto the front panel of the console for each dialysis treatment (**Figure 1**).



**Figure 1. Tablo Cartridge Inserted into Tablo Hemodialysis Delivery System**

## V. INDICATIONS FOR USE

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 Cartridge has the same fundamental technology, principle of operation, and principal functionality as the predicate device. The Tablo Cartridge is a blood tubing set which functions as part of the extracorporeal blood system of the Tablo Hemodialysis machine.

The Tablo Cartridge with E-beam sterilization (Modified Device) and the Predicate Device are equivalent in technological characteristics:

- Intended use – To provide extra-corporeal access during hemodialysis.
- Operating principle – Inserted onto Tablo Console as part of the extracorporeal blood system.
- Compatibility – Interface with the Tablo Console (Hemodialysis System).

The following differences exist between the subject and predicate device:

- Sterilization method changed from Ethylene Oxide (EO) gas to E-beam radiation.
- Minor design changes for improvement.

## VII. PERFORMANCE DATA

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

### E-Beam Sterilization Process Validation Testing

The E-beam sterilization process validation testing for the Tablo Cartridge was conducted in accordance with FDA guidance document, “Hemodialysis Blood Tubing Sets – Premarket Notification [510(k)] Submissions,” dated April 23, 2008 and “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile,” dated January 21, 2016.

The Tablo Cartridge complies with following standards:

- ISO 11137-1:2006 Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2:2013 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
- ISO 11737-1:2018 Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
- ISO 11737-2:2019 Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- USP <71> Sterility Tests standard
- ANSI/AAMI ST72:2019 Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing

The E-beam sterilization validation included the following tests to support the sterilization validation:

- Bioburden Recovery Test
- Bioburden Determination
- Verification Dose Determination
- Dose Map Study
- Method Suitability Determination
- Test of Sterility

#### **Shelf-Life Testing (Accelerated Aging and Transit)**

The shelf-life verification for the Tablo Cartridge was conducted as recommended by FDA’s guidance document, “Hemodialysis Blood Tubing Sets – Premarket Notification [510(k)] Submissions,” dated April 23, 2008.

The shelf-life verification testing included the following tests to ensure that the Tablo Cartridge complies with the ISO 11607-1:2019 and ISO 11607-2:2019 standards:

- Accelerated aging testing
- Climatic conditioning testing
- Gross leak detection (Bubble) testing
- Seal strength (Peel) testing
- Package performance testing
- Product functional testing

#### **Biocompatibility Testing**

The biocompatibility evaluation for the Tablo Cartridge 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 testing included the following tests and continues to be supportive for the modified device, per ISO 10993-1:2018, as an external communicating device with prolonged direct and indirect contact (>24 hours to 30 days) with the blood path:

- Cytotoxicity
- Sensitization
- Irritation
- Acute systemic toxicity
- Hemocompatibility
- Genotoxicity
- Pyrogenicity

**Bench Performance Testing**

The bench performance testing for the Tablo Cartridge was conducted in accordance with the FDA guidance document, "Hemodialysis Blood Tubing Sets – Premarket Notification [510(k)] Submissions," dated April 23, 2008.

Nonclinical bench performance tests were conducted to demonstrate that the Tablo Cartridge meets the system requirements and performs as intended.

**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. CONCLUSION**

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