DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	1/17/2023-2/10/2023*
	FEI NUMBER 3010355846

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Leslie L. Trigg, CEO and Chair

FIRM NAME	STREET ADDRESS
Outset Medical, Inc.	3052 Orchard Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Jose, CA 95134-2011	Specification Developer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, Outset Medical, Inc. failed to submit a Medical Device Report for the patient death which occurred on (b) (6), (b) (7)(C) during Tablo hemodialysis treatment, Console Serial Number (b) (4), at the (b) (4) Complaint Record COM-0000000710 documents that the treating team or physician stated it was unknown whether the event was attributed to patient or Tablo machine. In addition, the device logfile was not available to demonstrate that a malfunction did not occur during treatment.

OBSERVATION 2

Validation of device software is incomplete.

Specifically, Outset Medical, Inc. failed to close issues identified during thirteen software updates (b) (4) to the Tablo Hemodialysis System, prior to final approval of the Software Verification and Regression Test Reports. Outset Medical, Inc. SOP-1979, titled "Issue Tracking Procedure", Revision G, Released 11/14/2022,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Suzanne M Healy, Consumer Safety Officer Maida Henesian, Investigator Anil K Kochhar, FDA Center Employee	X Suzanne M Healy Consumer Safety Officer Signed By: Suzanne M. Healy -S Date Signed: 02-10-2023 11:50:14	2/10/2023

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states that after issues have been verified, the Change Control Board must review and evaluate prior to closure in the (b) (4) software system. For example, Outset Medical, Inc. test report titled "Tablo X 4.9.1 Console Software Verification and Regression Test Report", DOC-0005851, Revision 1, Released 7/30/2020, contains two unresolved software anomalies and thirty-three issues wit (b) (4) status "verified", not "closed", at the time the final report was approved and the software version was released.

OBSERVATION 3

Procedures that define the responsibility for review and the authority for the disposition of nonconforming product have not been adequately established.

Specifically, Outset Medical, Inc. procedure titled "Product Nonconforming Process", SOP-0016, Revision J, Released 2/19/2021, failed to provide clearly defined instructions for documenting root cause investigations, as well as, proposed preventive actions in the CAPA system. For example, Outset Production Non-conformance Record NC-01033 documents the blood pump assembly sensor failure and thermal event that occurred on 4/21/2021 at the Outset Medical Manufacturing facility in Mexico. The investigation section of NC-01033 states tha (b) (4)(SQA-8032) was opened to investigate the root cause and verify if the issue could affect other consoles in the future. The (b) (4) software tracking system investigation failed to prevent a similar thermal event which occurred in the field on 8/4/2021.

OBSERVATION 4

Corrective and preventive action activities and/or results have not been documented.

Specifically, Outset Medical, Inc. failed to document nine issues identified in customer complaints as Corrective and Preventive Actions. The identified device issues were documented in th (b) (4) software system as SQAs. For example, Customer Complaint Record COM-0000001754, received 8/19/2022, documents that a blood pump guidewire was bent by users because the lever is too

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difficult to pull and the Field Service Engineer stated improvements to unload efficiency were being tracked through SQA-5981.

***DATES OF INSPECTION**

1/17/2023(Tue), 1/18/2023(Wed), 1/19/2023(Thu), 1/20/2023(Fri), 1/24/2023(Tue), 1/25/2023(Wed), 1/26/2023(Thu), 2/01/2023(Wed), 2/02/2023(Thu), 2/07/2023(Tue), 2/10/2023(Fri)

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Annotations to Observations

Observation 1:

Observation 2:

Observation 3:

Observation 4:

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."