# Outset Medical's TabloCart with Prefiltration Receives FDA 510(k) Clearance

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SAN JOSE, Calif.--(BUSINESS WIRE)--May 6, 2024-- Outset Medical, Inc. (Nasdaq: OM) (“Outset”), a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis, announced today that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance of TabloCart™ with prefiltration, an innovative optional accessory for the Tablo® Hemodialysis System.

Outset has resumed distribution of TabloCart with prefiltration and has product available to ship to customers in the United States.

"With the FDA's clearance of TabloCart with prefiltration, we have delivered features to the Tablo Hemodialysis System that increase the flexibility for nurses and health systems to serve patients from the ICU to the bedside,” said Leslie Trigg, Chair and CEO of Outset Medical. “Today's announcement underscores Outset Medical's commitment to innovation and our ongoing dedication to transforming the landscape of dialysis treatment.”

TabloCart is designed to enhance the user experience within healthcare facilities. It comes in two versions: one with added storage and another featuring water prefiltration capabilities, meeting diverse clinical needs. Key features of TabloCart include:

- **Versatile prefiltration**: With its three customizable prefiltration options, TabloCart is designed to adapt to varying water conditions and also features a booster pump to increase incoming water pressure.
- **Enhanced maneuverability**: Equipped with 360-degree rotating wheels and directional locking rear wheels, it facilitates seamless movement through various clinical environments.

TabloCart is an innovative optional accessory that complements the Tablo Hemodialysis System. Tablo, which is used from the hospital to the home, represents a significant technological advancement that transforms the dialysis experience for patients, and operationally simplifies it for providers. Requiring only access to tap water and a standard electrical outlet, Tablo serves as a single enterprise solution that can be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere and by virtually anyone.

**About Outset Medical, Inc.**

Outset is a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis. The Tablo Hemodialysis System, FDA cleared for use from the hospital to the home, represents a significant technological advancement that transforms the dialysis experience for patients and operationally simplifies it for providers. Tablo serves as a single enterprise solution that can be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere and by anyone. The integration of water purification and on-demand dialysate production enables Tablo to serve as a dialysis clinic on wheels, with 2-way wireless data transmission and a proprietary data analytics platform powering a new holistic approach to dialysis care. Tablo is a registered trademark of Outset Medical, Inc.

Indications for Use

The Tablo® Hemodialysis System and TabloCart™ 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 and observed by a trained individual who is considered competent in the use of the device. The Tablo Hemodialysis System is also indicated for use in the home. Treatment types available include Intermittent Hemodialysis (IHD), Sustained Low Efficiency Dialysis (SLED/ SLEDD), Prolonged Intermittent Renal Replacement Therapy (PIRRT), and Isolated Ultrafiltration.

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