

09 Aug 2023 | News

# July Warning Letter Prompts Pause In Dialysis Accessory Distribution

by [Brian Bossetta](#)

Following a recent warning letter from the US Food and Drug Administration, Outset Medical has stopped distribution of the TabloCart, an accessory to its Tablo Hemodialysis System.

In response to a July [warning letter](#) from the US Food and Drug Administration, Outset Medical has decided to pause shipments of its TabloCart with Prefiltration (TabloCart) until the company secures 510(k) clearance for marketing authorization, the company [announced](#) in second quarter financial results.

Lacking 510(k) clearance for the TabloCart was one of two concerns cited by the FDA in its July letter to the company. (Also see "[FDA Sends Warning To Outset Medical Concerning Two Issues With Its Dialysis Device](#)" - Medtech Insight, 10 Jul, 2023.)

"Since receiving the warning letter on July 6, we have made the decision to file a 510(k) for TabloCart with Prefiltration and pause distribution of the product until a 510(k) clearance has been granted," said Leslie Trigg, Outset CEO.

The San Jose, CA-based medical technology company added that it plans to file the 510(k) this month.

While Trigg added that Outset expects to see its "strong momentum both in the acute and home end markets to continue to drive the business" in the second half of the year, the company acknowledged that halting TabloCart distribution would negatively impact revenue.

Though the company's estimated 2023 revenue remains between \$144m and \$150m, putting the brakes on distribution will likely result in the company hitting closer to the low end of that range.

For the second quarter of 2023, Outset posted revenue of \$36m, a 44% increase from the second quarter of 2022, while the company's total gross profit for the quarter was \$7.7m compared to \$3.8m in 2022. Its total gross margin was 21% compared to 15% in 2022.

In its July letter to the company, the FDA also warned Outset that materials on the company's website promoted continuous renal replacement therapy (CRRT), a slower type of dialysis that is said to put less stress on the heart. The Tablo system does not have an indication for CRRT, which is done over a 24-hour period instead of the usual four hours. Outset said that concern would be "effectively addressed" through labeling and promotional changes.

In November 2021, the Tablo Hemodialysis System was the first technology granted Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES), a designation created for US Medicare kidney patients. (Also see "[At-Home Dialysis System Gets Landmark Medicare Designation](#)" - Medtech Insight, 2 Nov, 2021.)