

**K232776 Tablo® Hemodialysis System**May 3, 2024  
235 days to decisionK232776 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k232776/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Sep 11, 2023
Decision date	May 3, 2024
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	TabloCart™ with Prefiltration Drawer

**APPLICANT**

---

Company	<b>Outset Medical, Inc.</b>
Location	San Jose, CA, US
Contact	Joshua Mink
510(k) history	9 submissions · 9 cleared · 2016-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232776/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026