

**K223248 Tablo® Hemodialysis System**Jun 21, 2023  
243 days to decisionK223248 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k223248/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Oct 21, 2022
Decision date	Jun 21, 2023
Days to decision	243 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223248/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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