

**K233335 Tablo® Hemodialysis System**Dec 5, 2023  
67 days to decisionK233335 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k233335/>**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	Sep 29, 2023
Decision date	Dec 5, 2023
Days to decision	67 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	Claire Bao
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/k233335/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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