

K211370 Tablo Hemodialysis SystemJul 29, 2022
451 days to decisionK211370 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k211370/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	May 4, 2021
Decision date	Jul 29, 2022
Days to decision	451 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211370/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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