

**K200741 Tablo Hemodialysis System**Mar 31, 2020  
8 days to decisionK200741 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k200741/>**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	Mar 23, 2020
Decision date	Mar 31, 2020
Days to decision	8 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Outset Medical, Inc.</b>
Location	San Jose, CA, US
Contact	Jennifer Mascioli-Tudor
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/k200741/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026