

K190793 Tablo Hemodialysis System, Tablo CartridgeDec 12, 2019
259 days to decisionK190793 · Product code: **KDI** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190793/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 28, 2019
Decision date	Dec 12, 2019
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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