

K160881 Tablo ConsoleNov 15, 2016
230 days to decisionK160881 · Product code: **KDI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k160881/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 30, 2016
Decision date	Nov 15, 2016
Days to decision	230 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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