

**K150880 Tablo Console with Wireless Capability**May 1, 2015  
30 days to decisionK150880 · Product code: **KDI** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k150880/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Apr 1, 2015
Decision date	May 1, 2015
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Outset Medical</b>
Location	San Jose, CA, US
Contact	Nancy Gallo
510(k) history	1 submissions · 1 cleared · 2015-2015

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150880/> 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 June 4, 2026