

K121736 PERF-GEN PULSATILE PERFUSION SOLUTIONAug 16, 2013
429 days to decisionK121736 · Product code: **KDL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k121736/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Perfusion, Kidney, Disposable (KDL)
Date received	Jun 13, 2012
Decision date	Aug 16, 2013
Days to decision	429 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Waters Medical Systems, LLC
Location	Rochester, MN, US
Contact	ROBERT WARREN
510(k) history	3 submissions · 3 cleared · 2012-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121736/> Data sourced from FDA 510(k) public records (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. - Generated June 8, 2026