

K111521 WAVESFeb 16, 2012
260 days to decisionK111521 · Product code: **KDN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k111521/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Perfusion, Kidney (KDN)
Date received	Jun 1, 2011
Decision date	Feb 16, 2012
Days to decision	260 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

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