

K121618 BEL-GEN COLD STORAGE SOLUTIONJun 14, 2013
378 days to decisionK121618 · Product code: **KDL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k121618/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Perfusion, Kidney, Disposable (KDL)
Date received	Jun 1, 2012
Decision date	Jun 14, 2013
Days to decision	378 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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