

K171482 NEPHROCHECK Test SystemNov 16, 2017
181 days to decisionK171482 · Product code: **PIG** · Chemistry
Source: <https://www.510kdatabase.net/k171482/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acute Kidney Injury Test System (PIG)
Date received	May 19, 2017
Decision date	Nov 16, 2017
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Astute Medical, Inc.
Location	San Diego, CA, US
Contact	Karin Hughes
510(k) history	3 submissions · 2 cleared · 2014-2017

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