

K153683 Trak Male Fertility Testing SystemMay 16, 2016
146 days to decisionK153683 · Product code: **POV** · Hematology
Source: <https://www.510kdatabase.net/k153683/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Semen Analysis Device (POV)
Date received	Dec 22, 2015
Decision date	May 16, 2016
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sandstone Diagnostics, Inc.
Location	Livermore, CA, US
Contact	Greg Sommer
510(k) history	2 submissions · 2 cleared · 2016-2017

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