

K172514 Trak Plus Male Fertility Testing SystemNov 17, 2017
88 days to decisionK172514 · Product code: **POV** · Hematology
Source: <https://www.510kdatabase.net/k172514/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Semen Analysis Device (POV)
Date received	Aug 21, 2017
Decision date	Nov 17, 2017
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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