

K161493 YO Home Sperm TestNov 8, 2016
160 days to decisionK161493 · Product code: **POV** · Hematology
Source: <https://www.510kdatabase.net/k161493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Semen Analysis Device (POV)
Date received	Jun 1, 2016
Decision date	Nov 8, 2016
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medical Electronic Systems , Ltd.
Location	Los Altos, CA, US
Contact	MARCIA DEUTSCH
510(k) history	5 submissions · 5 cleared · 2007-2025

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