

**K241628 YO Home Sperm Test**Nov 29, 2024  
176 days to decisionK241628 · Product code: **POV** · Hematology  
Source: <https://www.510kdatabase.net/k241628/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Semen Analysis Device (POV)
Date received	Jun 6, 2024
Decision date	Nov 29, 2024
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medical Electronic Systems , Ltd.</b>
Location	Los Altos, CA, US
Contact	Taly Vider Cohen
510(k) history	5 submissions · 5 cleared · 2007-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241628/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026