

**K243114 SQA-iOw Sperm Quality Analyzer**May 2, 2025  
214 days to decisionK243114 · Product code: **POV** · Hematology  
Source: <https://www.510kdatabase.net/k243114/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Semen Analysis Device (POV)
Date received	Sep 30, 2024
Decision date	May 2, 2025
Days to decision	214 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/k243114/> 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