

**K252228 Seaman Pro/Seaman**Apr 9, 2026  
267 days to decisionK252228 · Product code: **POV** · Hematology  
Source: <https://www.510kdatabase.net/k252228/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Semen Analysis Device (POV)
Date received	Jul 16, 2025
Decision date	Apr 9, 2026
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Checkcells, Inc.</b>
Location	Santa Monica, CA, US
Contact	Martin Kosela
Website	<a href="https://www.checkcells.com">https://www.checkcells.com</a>
510(k) history	1 submissions · 1 cleared · 2026-2026

Checkcells, Inc. develops AI-powered diagnostic systems for clinical laboratories. The company specializes in automated cell detection and analysis, with a manufacturing facility in Santa Monica, California. Checkcells has received FDA 510(k) clearance from total submission. The company's regulatory focus is Hematology devices. The cleared device, Seaman Pro/Seaman, represents the company's entry into FDA-regulated diagnostics. Latest clearance occurred in 2026, confirming active regulatory engagement. Checkcells applies AI and robotics to streamline laboratory workflows....