FDA 510(k) Premarket Notification

K243114 SQA-iOw Sperm Quality Analyzer

CLEARED

May 2, 2025
214 days to decision

K243114 · Product code: **POV** · Hematology
Source: https://www.510kdatabase.net/k243114/

SUBMISSION DETAILS

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

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