FDA 510(k) Premarket Notification

K241628 YO Home Sperm Test

CLEARED

Nov 29, 2024
176 days to decision

K241628 · Product code: **POV** · Hematology
Source: https://www.510kdatabase.net/k241628/

SUBMISSION DETAILS

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

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