

K063864 QWIKCHECK TEST STRIPS- REAGENT STRIPS FOR SEMEN ANALYSISMar 26, 2007
87 days to decisionK063864 · Product code: **POV** · Hematology
Source: <https://www.510kdatabase.net/k063864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Semen Analysis Device (POV)
Date received	Dec 29, 2006
Decision date	Mar 26, 2007
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medical Electronic Systems , Ltd.
Location	Los Altos, CA, US
Contact	Erika B Ammirati
510(k) history	5 submissions · 5 cleared · 2007-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063864/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026