

K100341 SPERM CHECK FERTILITYMay 4, 2010
88 days to decisionK100341 · Product code: **POV** · Hematology
Source: <https://www.510kdatabase.net/k100341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Semen Analysis Device (POV)
Date received	Feb 5, 2010
Decision date	May 4, 2010
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Princeton BioMeditech Corp.
Location	Monmouth Junction, NJ, US
Contact	KYUNG-AH KIM
510(k) history	72 submissions · 72 cleared · 1994-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100341/> 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