

**K011679 FERTILMARQ HOME DIAGNOSTIC SCREENING TEST
KIT FOR MALE INFERTILITY**Aug 15, 2001
77 days to decisionK011679 · Product code: **POV** · Hematology
Source: <https://www.510kdatabase.net/k011679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Semen Analysis Device (POV)
Date received	May 30, 2001
Decision date	Aug 15, 2001
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Embryotech Laboratories, Inc.
Location	Wayland, MA, US
Contact	ANN D MCGONIGLE
510(k) history	2 submissions · 2 cleared · 1998-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011679/>; 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 June 28, 2026