

K960648 PHEM-CHEKMay 13, 1996
89 days to decisionK960648 · Product code: **LNW** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k960648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Paper, Obstetric Ph (LNW)
Date received	Feb 14, 1996
Decision date	May 13, 1996
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Femtek, Inc.
Location	Pasadena, CA, US
Contact	JAMES C CAILLOUETTE, MD
510(k) history	1 submissions · 1 cleared · 1996-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k960648/> 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 29, 2026