FDA 510(k) Premarket Notification

K960648 PHEM-CHEK

CLEARED

May 13, 1996
89 days to decision

K960648 · Product code: **LNW** · Obstetrics & Gynecology
Source: 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