

K012230 PHEM-ALERTOct 9, 2001
85 days to decisionK012230 · Product code: **LNW** · Chemistry
Source: <https://www.510kdatabase.net/k012230/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Paper, Obstetric Ph (LNW)
Date received	Jul 16, 2001
Decision date	Oct 9, 2001
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Femtek,Llc.
Location	Rockville, MD, US
Contact	JOEL S FADEN
510(k) history	2 submissions · 2 cleared · 2001-2003

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