FDA 510(k) Premarket Notification

K122907 FASTEP AT-HOME PREGNANCY, HCG, OVER THE COUNTER

CLEARED

Mar 14, 2013
174 days to decision

K122907 · Product code: **LCX** · Chemistry
Source: https://www.510kdatabase.net/k122907/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Sep 21, 2012
Decision date	Mar 14, 2013
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Polymed Therapeutics, Inc.**
Location	Mission Viejo, CA, US
Contact	TERRI WALLACE
510(k) history	5 submissions · 5 cleared · 2012-2014