

**K112101 FASTEP HCG PREGANCY SERUM/URINE CASSETTE  
AND DIPSTICK TESTS**Jul 17, 2012  
361 days to decisionK112101 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k112101/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jul 22, 2011
Decision date	Jul 17, 2012
Days to decision	361 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112101/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 6, 2026