

K132834 FASTEP S10 HCG SERUM/URINE COMBO TESTJan 9, 2014
121 days to decisionK132834 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k132834/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Sep 10, 2013
Decision date	Jan 9, 2014
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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