

K112315 HOME PREGNANCY TESTApr 23, 2012
256 days to decisionK112315 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k112315/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 11, 2011
Decision date	Apr 23, 2012
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Newsen Coast Bio-Pharmaceutical Co., Ltd.
Location	Simi Valley, CA, US
Contact	CHANDRAVADAN PATEL
510(k) history	1 submissions · 1 cleared · 2012-2012

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