

K123844 CHEMTRUE HCG PREGNANCY URINE DIPSTICK, HCG PREGNANCY URINE CASSETTE TEST, AND HCG COMBO SERUM/URINE CASSETTE TESTMay 30, 2013
168 days to decisionK123844 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k123844/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Dec 13, 2012
Decision date	May 30, 2013
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chemtron Biotech, Inc.
Location	San Diego, CA, US
Contact	Jane Zhang
510(k) history	11 submissions · 11 cleared · 2011-2023

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