

K043385 OSOM HCG COMBO TESTApr 12, 2005
124 days to decisionK043385 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k043385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Dec 9, 2004
Decision date	Apr 12, 2005
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genzyme Diagnostics
Location	San Diego, CA, US
Contact	E.V. GOORCHENKO
510(k) history	5 submissions · 5 cleared · 1996-2005

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