

K964155 CONTRAST HCG URINE/SERUM TEST AND RAPID HCG URINE/SERUM TESTNov 25, 1996
40 days to decisionK964155 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k964155/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Oct 16, 1996
Decision date	Nov 25, 1996
Days to decision	40 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genzyme Diagnostics
Location	San Diego, CA, US
Contact	DELIA R BETHELL
510(k) history	5 submissions · 5 cleared · 1996-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964155/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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