

K981838 ACCUSTRIP HCG-URINE MODEL NUMBER HCG-002Jun 25, 1998
30 days to decisionK981838 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k981838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	May 26, 1998
Decision date	Jun 25, 1998
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Unotech Diagnostics, Inc.
Location	San Leandro, CA, US
Contact	KEN WU
510(k) history	3 submissions · 3 cleared · 1997-2003

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