

**K032987 ACCUTEST HCG-COMBO MODEL,HCG-004,  
ACCUSTRIP HCG-COMBO MODEL, HCG-005**

Nov 17, 2003  
54 days to decision

K032987 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k032987/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Sep 24, 2003
Decision date	Nov 17, 2003
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k032987/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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