

**K971886 ACCUTEST HCG-URINE**Jun 11, 1997  
20 days to decisionK971886 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k971886/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	May 22, 1997
Decision date	Jun 11, 1997
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971886/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026