

**K062361 INNOVACON HCG UKTRA TEST DEVICE**Oct 23, 2006  
70 days to decisionK062361 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k062361/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 14, 2006
Decision date	Oct 23, 2006
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Innovacon, Inc.</b>
Location	San Diego, CA, US
Contact	EDWARD TUNG
510(k) history	3 submissions · 3 cleared · 2006-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062361/> 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 28, 2026