

**K964461 ONE -STEP URINE/SERUM COMBO PREGNANCY  
CARD TEST**Feb 11, 1997  
96 days to decisionK964461 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k964461/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Nov 7, 1996
Decision date	Feb 11, 1997
Days to decision	96 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Teco Diagnostics</b>
Location	Placentia, CA, US
Contact	ANDREW REAMS
510(k) history	51 submissions · 51 cleared · 1993-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964461/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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