

**K955353 ONE STEP PREGNANCY HCG SERUN DILUENT REAGENT**Mar 19, 1996  
119 days to decisionK955353 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k955353/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Nov 21, 1995
Decision date	Mar 19, 1996
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tcpi, Inc.</b>
Location	Ft. Lauderdale, FL, US
Contact	CLEVE W LAIRD
510(k) history	14 submissions · 14 cleared · 1992-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k955353/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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