

**K953486 MIT ONE STEP PREGNANCY TEST**Dec 21, 1995  
149 days to decisionK953486 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k953486/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jul 25, 1995
Decision date	Dec 21, 1995
Days to decision	149 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>3c Diagnostics, Inc.</b>
Location	Hsin Chu, R.O.C., TW
Contact	Z EIGNER
510(k) history	1 submissions · 1 cleared · 1995-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k953486/> 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 July 1, 2026