

**K950354 HUMAN CHORIONIC GONADOTROPIN (HCG) TEST  
SYSTEM FOR THE EARLY DETECTION OF PREGNANCY**Jul 19, 1995  
170 days to decisionK950354 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k950354/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Jan 30, 1995
Decision date	Jul 19, 1995
Days to decision	170 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>MI Strategies, Inc.</b>
Location	Boston, MA, US
Contact	CAROLYN S LANGER
510(k) history	4 submissions · 4 cleared · 1995-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950354/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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