

K011551 SURE CHECK PREGNANCY TESTAug 14, 2001
88 days to decisionK011551 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k011551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	May 18, 2001
Decision date	Aug 14, 2001
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Chembio Diagnostic Systems, Inc.
Location	Medford, NY, US
Contact	FRAN WHITE
510(k) history	6 submissions · 6 cleared · 1992-2001

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