

K053138 MYSET PREGNANCY TESTMar 1, 2006
112 days to decisionK053138 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k053138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Nov 9, 2005
Decision date	Mar 1, 2006
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ani Biotech OY
Location	Beverly, MA, US
Contact	FRAN WHITE
510(k) history	1 submissions · 1 cleared · 2006-2006

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