

K142754 Surearly Pregnancy Test Strip, Surearly Digital Pregnancy TestApr 7, 2016
560 days to decisionK142754 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k142754/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Sep 25, 2014
Decision date	Apr 7, 2016
Days to decision	560 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sugentech, Inc.
Location	Daejeon, KR
Contact	Mijin Sohn
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142754/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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