

K172627 David Home Pregnancy Test Cassette, David Professional Pregnancy Test CassetteMar 28, 2018
208 days to decisionK172627 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k172627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Sep 1, 2017
Decision date	Mar 28, 2018
Days to decision	208 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Runbio Biotech Co.,Ltd
Location	Tacoma, WA, US
Contact	Chandler Chen
510(k) history	3 submissions · 3 cleared · 2006-2019

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