

**K181551 DAVID One Step Home Use Pregnancy Test
 Midstream, DAVID One Step Home Use Pregnancy Test Strip,
 DAVID One Step Prescription Pregnancy Test Strip, DAVID One
 Step Prescription Pregnancy Test Cassette, DAVID One Step
 Home Use Pregnancy Test Cassette**

Feb 22, 2019
 254 days to decision

K181551 · Product code: **LCX** · Chemistry
 Source: <https://www.510kdatabase.net/k181551/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Jun 13, 2018
Decision date	Feb 22, 2019
Days to decision	254 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	Lyn Chen
510(k) history	3 submissions · 3 cleared · 2006-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k181551/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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