

**K190705 WHOLEPOWER Pregnancy Rapid Test Cassette,
WHOLEPOWER Pregnancy Rapid Test Strip, WHOLEPOWER
Pregnancy Rapid Test Midstream**Apr 15, 2019
27 days to decisionK190705 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k190705/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Mar 19, 2019
Decision date	Apr 15, 2019
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wholepower Biotech Co., Ltd.
Location	Guangzhou, CN
Contact	William Gao
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Lsi International
Contact	Joe Shia

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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