

K192843 INNOVITA HCG Pregnancy Rapid Test Strip, INNOVITA HCG Pregnancy Rapid Test Cassette, INNOVITA HCG Pregnancy Rapid Test Midstream

Nov 22, 2019
50 days to decision

K192843 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k192843/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Oct 3, 2019
Decision date	Nov 22, 2019
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Innovita (Tangshan) Biological Technology Co., Ltd.
Location	Qian?An, CN
Contact	Leo Lee
510(k) history	3 submissions · 3 cleared · 2019-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k192843/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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