

K241919 Innovita HCG Pregnancy Rapid Combo TestAug 2, 2024
32 days to decisionK241919 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k241919/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jul 1, 2024
Decision date	Aug 2, 2024
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
Contact	Jenny Xia

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241919/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026