

K250398 Innovita Flu A/B Antigen Rapid TestJul 3, 2025
141 days to decisionK250398 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k250398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Devices Detecting Influenza A, B, And C Virus Antigens (PSZ)
Date received	Feb 12, 2025
Decision date	Jul 3, 2025
Days to decision	141 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

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