

K251538 Status™ COVID-19/Flu A&BNov 14, 2025
179 days to decisionK251538 · Product code: **SCA** · Microbiology
Source: <https://www.510kdatabase.net/k251538/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Multi-analyte Respiratory Virus Antigen Detection Test (SCA)
Date received	May 19, 2025
Decision date	Nov 14, 2025
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Princeton BioMeditech Corp.
Location	Monmouth Junction, NJ, US
Contact	Young-A Kim
510(k) history	72 submissions · 72 cleared · 1994-2025

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