

**K220801 ID Now Instrument, ID Now Influenza A & B 2, ID NOW
Strep A 2**

Jun 24, 2022
98 days to decision

K220801 · Product code: **OZE** · Microbiology
Source: <https://www.510kdatabase.net/k220801/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Influenza A And Influenza B Multiplex Nucleic Acid Assay (OZE)
Date received	Mar 18, 2022
Decision date	Jun 24, 2022
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Diagnostics Scarborough, Inc.
Location	Scarborough, ME, US
Contact	Jessica Stahle
510(k) history	6 submissions · 6 cleared · 2019-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k220801/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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