

K190204 ID NOW Influenza A & B 2Mar 18, 2019
42 days to decisionK190204 · Product code: **OZE** · Microbiology
Source: <https://www.510kdatabase.net/k190204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Influenza A And Influenza B Multiplex Nucleic Acid Assay (OZE)
Date received	Feb 4, 2019
Decision date	Mar 18, 2019
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Alere Scarborough, Inc.
Location	Scarborough, ME, US
Contact	Angela Drysdale
510(k) history	17 submissions · 16 cleared · 2012-2019

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