

K181736 CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel: Influenza B Lineage Genotyping Kit,

Jul 30, 2018
28 days to decision

K181736 · Product code: **OZE** · Microbiology
Source: <https://www.510kdatabase.net/k181736/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Influenza A And Influenza B Multiplex Nucleic Acid Assay (OZE)
Date received	Jul 2, 2018
Decision date	Jul 30, 2018
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Centers For Disease Control and Prevention (Cdc)
Location	Atlanta, GA, US
Contact	Yon Yu
510(k) history	6 submissions · 5 cleared · 2014-2018

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k181736/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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