

K161556 CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel, Influenza A Subtyping KitJun 30, 2016
24 days to decisionK161556 · Product code: **OZE** · Microbiology
Source: <https://www.510kdatabase.net/k161556/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Influenza A And Influenza B Multiplex Nucleic Acid Assay (OZE)
Date received	Jun 6, 2016
Decision date	Jun 30, 2016
Days to decision	24 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.netDevice record: <https://www.510kdatabase.net/k161556/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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