

K171641 Accula Flu A/Flu B TestFeb 6, 2018
249 days to decisionK171641 · Product code: **OZE** · Microbiology
Source: <https://www.510kdatabase.net/k171641/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Influenza A And Influenza B Multiplex Nucleic Acid Assay (OZE)
Date received	Jun 2, 2017
Decision date	Feb 6, 2018
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mesa Biotech, Inc.
Location	San Diego, CA, US
Contact	Barbara E. Stevens
510(k) history	3 submissions · 3 cleared · 2018-2020

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