

K181443 Accula RSV TestNov 23, 2018
176 days to decisionK181443 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k181443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	May 31, 2018
Decision date	Nov 23, 2018
Days to decision	176 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 Stevens
510(k) history	3 submissions · 3 cleared · 2018-2020

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