

K163636 ePlex Respiratory Pathogen PanelJun 9, 2017
169 days to decisionK163636 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k163636/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Dec 22, 2016
Decision date	Jun 9, 2017
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genmark Diagnostics, Incorporated
Location	Carlsbad, CA, US
Contact	ALAN MADERAZO
510(k) history	7 submissions · 7 cleared · 2016-2022

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