

K143653 Verigene Respiratory Pathogens Flex Nucleic Acid Test (RP Flex)Sep 4, 2015
255 days to decisionK143653 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k143653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Dec 23, 2014
Decision date	Sep 4, 2015
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nanosphere, Inc.
Location	Northbrook, IL, US
Contact	Noah Lerner
510(k) history	16 submissions · 15 cleared · 2007-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143653/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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