

K103209 VERIGENE RESPIRATORY VIRUS NUCLEIC ACID TEST +(RVNAT+)

Jan 10, 2011
70 days to decision

K103209 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k103209/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Nov 1, 2010
Decision date	Jan 10, 2011
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k103209/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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