

**K092957 VERIGENE SYSTEM, VERIGENE RESPIRATORY
VIRUS NUCLEIC ACID TEST**Oct 21, 2009
26 days to decisionK092957 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k092957/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Sep 25, 2009
Decision date	Oct 21, 2009
Days to decision	26 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092957/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026