

K083088 VERIGENE RESPIRATORY VIRUS NUCLEIC ACID TESTMay 1, 2009
197 days to decisionK083088 · Product code: **OCC** · Microbiology
Source: <https://www.510kdatabase.net/k083088/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Oct 16, 2008
Decision date	May 1, 2009
Days to decision	197 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.netDevice record: <https://www.510kdatabase.net/k083088/> 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