

**K122514 VERIGENE GRAM-POSITIVE BLOOD CULTURE (GC-
GP) NUCLEIC ACID TEST**Sep 19, 2012
33 days to decisionK122514 · Product code: **PAM** · Microbiology
Source: <https://www.510kdatabase.net/k122514/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gram-positive Bacteria And Their Resistance Markers (PAM)
Date received	Aug 17, 2012
Decision date	Sep 19, 2012
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122514/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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