

K132843 VERIGENE GRAM NEGATIVE BLOOD CULTURE NUCLEIC ACID TEST (BC-GN)

Jan 8, 2014
120 days to decision

K132843 · Product code: **PEN** · Microbiology
Source: <https://www.510kdatabase.net/k132843/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gram-negative Bacteria And Associated Resistance Markers (PEN)
Date received	Sep 10, 2013
Decision date	Jan 8, 2014
Days to decision	120 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.net

Device record: <https://www.510kdatabase.net/k132843/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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