

**K140083 VERIGENE ENTERIC PATHOGEN NUCLEIC ACID TEST  
( EP)**Jun 20, 2014  
158 days to decisionK140083 · Product code: **PCH** · Microbiology  
Source: <https://www.510kdatabase.net/k140083/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-based Assay System (PCH)
Date received	Jan 13, 2014
Decision date	Jun 20, 2014
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nanosphere, Inc.</b>
Location	Northbrook, IL, US
Contact	Teresa Raich
510(k) history	16 submissions · 15 cleared · 2007-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140083/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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