

**K070597 VERIGENE SYSTEM, F2 NUCLEIC ACID TEST, F5 NUCLEIC ACID TEST, AND MTHFR NUCLEIC ACID TEST**Oct 11, 2007  
223 days to decisionK070597 · Product code: **NSU** · Hematology  
Source: <https://www.510kdatabase.net/k070597/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrumentation For Clinical Multiplex Test Systems (NSU)
Date received	Mar 2, 2007
Decision date	Oct 11, 2007
Days to decision	223 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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