

**K070804 VERIGENE SYSTEM, VERIGENE WARFARIN
METABOLISM NUCLEIC ACID TEST**Sep 17, 2007
178 days to decisionK070804 · Product code: **ODW** · Toxicology
Source: <https://www.510kdatabase.net/k070804/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cytochrome P450 2c9 (cyp450 2c9) Drug Metabolizing Enzyme Genotyping System (ODW)
Date received	Mar 23, 2007
Decision date	Sep 17, 2007
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k070804/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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