

**K071867 RAPID GENOTYPING ASSAY -CYP2C9 & VKORC1,  
MODEL CATALOG NO. 006+0203 GACTGA**Apr 28, 2008  
297 days to decisionK071867 · Product code: **ODV** · Toxicology  
Source: <https://www.510kdatabase.net/k071867/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vitamin K Epoxide Reductase Complex Subunit One (vkorc1) Genotyping System (ODV)
Date received	Jul 6, 2007
Decision date	Apr 28, 2008
Days to decision	297 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Paragondx, LLC</b>
Location	Morrisville, NC, US
Contact	DEBORAH N KLOOS
510(k) history	1 submissions · 1 cleared · 2008-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k071867/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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