

**K040101 MODIFICATION TO DIADEXUS PLAC TEST**Feb 5, 2004  
16 days to decisionK040101 · Product code: **NOE** · Chemistry  
Source: <https://www.510kdatabase.net/k040101/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, System, Immunoassay, Lipoprotein-associated Phospholipase A2 (NOE)
Date received	Jan 20, 2004
Decision date	Feb 5, 2004
Days to decision	16 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Diadexus, Inc.</b>
Location	South San Francisco, CA, US
Contact	ROBERT L WOLFERT
510(k) history	7 submissions · 7 cleared · 2003-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040101/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 5, 2026