

**K914777 SIGMA PROCEDURE NO. 333-UV**Dec 27, 1991  
65 days to decisionK914777 · Product code: **DML** · Toxicology  
Source: <https://www.510kdatabase.net/k914777/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad-nadh, Specific Reagent For Alcohol Enzyme Method (DML)
Date received	Oct 23, 1991
Decision date	Dec 27, 1991
Days to decision	65 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	LEO BRESSLER
510(k) history	164 submissions · 164 cleared · 1984-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k914777/> 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 May 14, 2026