

**K964212 QUINIDINE ENZYME IMMUNOASSAY**Dec 18, 1996  
57 days to decisionK964212 · Product code: **LBZ** · Toxicology  
Source: <https://www.510kdatabase.net/k964212/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Quinidine (LBZ)
Date received	Oct 22, 1996
Decision date	Dec 18, 1996
Days to decision	57 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Diagnostic Reagents, Inc.</b>
Location	Walker, MI, US
Contact	YUH-GENG TSAY
510(k) history	66 submissions · 66 cleared · 1982-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964212/> 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 28, 2026