

**K992274 MODIFICATION TO IMX HOMOCYSTEINE**Oct 6, 1999  
92 days to decisionK992274 · Product code: **LPS** · Chemistry  
Source: <https://www.510kdatabase.net/k992274/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinary Homocystine (nonquantitative) Test System (LPS)
Date received	Jul 6, 1999
Decision date	Oct 6, 1999
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Axis Biochemicals, Asa</b>
Location	San Diego, CA, US
Contact	RONALD G LEONARDI
510(k) history	3 submissions · 3 cleared · 1998-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k992274/> 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 30, 2026