

K980907 AXIS HOMOCYSTEINE ENZYME IMMUNOASSAYOct 16, 1998
220 days to decisionK980907 · Product code: **LPS** · Chemistry
Source: <https://www.510kdatabase.net/k980907/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinary Homocystine (nonquantitative) Test System (LPS)
Date received	Mar 10, 1998
Decision date	Oct 16, 1998
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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