

K013606 ACS 180 HOMOCYSTEINE ASSAYDec 21, 2001
51 days to decisionK013606 · Product code: **LPS** · Chemistry
Source: <https://www.510kdatabase.net/k013606/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinary Homocystine (nonquantitative) Test System (LPS)
Date received	Oct 31, 2001
Decision date	Dec 21, 2001
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Diagnostics Corp.
Location	Medfield, MA, US
Contact	KENNETH T EDDES
510(k) history	32 submissions · 32 cleared · 2000-2003

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