

**K073640 ARCHITECT HOMOCYSTEINE REAGENTS,
CALIBRATORS AND CONTROLS**Apr 24, 2008
120 days to decisionK073640 · Product code: **LPS** · Chemistry
Source: <https://www.510kdatabase.net/k073640/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinary Homocystine (nonquantitative) Test System (LPS)
Date received	Dec 26, 2007
Decision date	Apr 24, 2008
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Axis-Shield Diagnostics, Ltd.
Location	Dundee, GB
Contact	Claire Dora
Website	http://www.axis-shield.com/
510(k) history	24 submissions · 24 cleared · 2002-2026

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