

**K112790 AXIS-SHIELD 3-REAGENT HOMOCYSTEINE ASSAY
FOR SYNCHRON**May 7, 2012
224 days to decisionK112790 · Product code: **LPS** · Chemistry
Source: <https://www.510kdatabase.net/k112790/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinary Homocystine (nonquantitative) Test System (LPS)
Date received	Sep 26, 2011
Decision date	May 7, 2012
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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