

**K083222 AXIS-SHIELD LIQUID STABLE (LS) 2-PART
HOMOCYSTEINE REAGENT, MODEL FHRK100**Jul 31, 2009
270 days to decisionK083222 · Product code: **LPS** · Chemistry
Source: <https://www.510kdatabase.net/k083222/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinary Homocystine (nonquantitative) Test System (LPS)
Date received	Nov 3, 2008
Decision date	Jul 31, 2009
Days to decision	270 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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