

**K072686 AXSYM HBA1C REAGENTS, AXSYM HBA1C CALIBRATORS, AXSYM HBA1C CONTROLS**Mar 17, 2008  
175 days to decisionK072686 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k072686/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Sep 24, 2007
Decision date	Mar 17, 2008
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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