

**K121946 AXIS-SHIELD ACVTIVE-B12**Mar 22, 2013  
262 days to decisionK121946 · Product code: **CDD** · Chemistry  
Source: <https://www.510kdatabase.net/k121946/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Jul 3, 2012
Decision date	Mar 22, 2013
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Axis-Shield Diagnostics, Ltd.</b>
Location	Dundee, GB
Contact	SIMON JOHN RICHARDS
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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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121946/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026