

**K160757 ADVIA Centaur Active-B12  
(Holotranscobalamin)(AB12) Assay, ADVIA Centaur Active-  
B12(AB12) Quality Control, and ADVIA Centaur Active-B12  
(AB12) Master Curve Materials (MCM)**Jul 26, 2016  
130 days to decisionK160757 · Product code: **CDD** · Chemistry  
Source: <https://www.510kdatabase.net/k160757/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Mar 18, 2016
Decision date	Jul 26, 2016
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Axis-Shield Diagnostics Limited</b>
Location	Dundee, GB
Contact	CLAIRE I. DORA
510(k) history	4 submissions · 4 cleared · 2016-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160757/> 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 June 21, 2026