

**K172133 ADVIA Centaur Active-B12 (Holotranscobalamin)
(AB12) Assay**Oct 27, 2017
105 days to decisionK172133 · Product code: **CDD** · Chemistry
Source: <https://www.510kdatabase.net/k172133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Jul 14, 2017
Decision date	Oct 27, 2017
Days to decision	105 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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