

K112443 ARCHITECT ACTIVE B-12 (HOLOTRANSCOBALAMIN)Dec 19, 2011
117 days to decisionK112443 · Product code: **CDD** · Chemistry
Source: <https://www.510kdatabase.net/k112443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Aug 24, 2011
Decision date	Dec 19, 2011
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Axis-Shield Diagnostics, Ltd.
Location	Dundee, GB
Contact	CLAIRE I DORA
Website	http://www.axis-shield.com/
510(k) history	24 submissions · 24 cleared · 2002-2026

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Device record: <https://www.510kdatabase.net/k112443/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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