

K233541 ARCHITECT Active-B12 (Holotranscobalamin)Jul 31, 2024
271 days to decisionK233541 · Product code: **CDD** · Chemistry
Source: <https://www.510kdatabase.net/k233541/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Nov 3, 2023
Decision date	Jul 31, 2024
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	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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