

**K062467 AXSYM HOLO TC REAGENT KIT, MODEL 3L83-20**Nov 22, 2006  
90 days to decisionK062467 · Product code: **CDD** · Chemistry  
Source: <https://www.510kdatabase.net/k062467/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Aug 24, 2006
Decision date	Nov 22, 2006
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary
Other names	STANDARD CALIBRATOR KIT, MODEL 3L83-01; CONTROL KIT, MODEL 3L83-10

**APPLICANT**

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Company	<b>Axis-Shield Diagnostics, Ltd.</b>
Location	Dundee, GB
Contact	ERICA CONWAY
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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