

K063347 AXSYM ANTI-CCP REAGENT, STANDARD CALIBRATOR AND CONTROL KITS, MODELS 3L91-20, 3L91-01 AND 3L91-10Mar 20, 2007
134 days to decisionK063347 · Product code: **NHX** · Immunology
Source: <https://www.510kdatabase.net/k063347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX)
Date received	Nov 6, 2006
Decision date	Mar 20, 2007
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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