

K083868 ARCHITECT ANTI-CCP (100 TEST), ARCHITECT ANTI-CCP (500 TEST), MODELS 1P65-25, 1P65-35Sep 25, 2009
270 days to decisionK083868 · Product code: **NHX** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX)
Date received	Dec 29, 2008
Decision date	Sep 25, 2009
Days to decision	270 days
Third-party review	No
Summary / Statement	Statement

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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