

**K110296 AXIS-SHIELD ANTI-CCP**Aug 18, 2011  
198 days to decisionK110296 · Product code: **NHX** · Immunology  
Source: <https://www.510kdatabase.net/k110296/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX)
Date received	Feb 1, 2011
Decision date	Aug 18, 2011
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110296/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026