

K153551 ADVIA Centaur Anti-CCP IgG (aCCP) assay including Reagents and Calibrators, Quality Controls and Master Curve Materials.Aug 4, 2016
237 days to decisionK153551 · Product code: **NHX** · Immunology
Source: <https://www.510kdatabase.net/k153551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX)
Date received	Dec 11, 2015
Decision date	Aug 4, 2016
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Axis-Shield Diagnostics Limited
Location	Dundee, GB
Contact	Claire I Dora
510(k) history	4 submissions · 4 cleared · 2016-2019

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