

**K021516 DIASTAT ANTI CYCLIC CITRULLINATED PEPTIDE
ELISA, MODEL FCCP 200**Jul 23, 2002
74 days to decisionK021516 · Product code: **NHX** · Immunology
Source: <https://www.510kdatabase.net/k021516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX)
Date received	May 10, 2002
Decision date	Jul 23, 2002
Days to decision	74 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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