

K093908 CCPOINTDec 1, 2010
344 days to decisionK093908 · Product code: **NHX** · Immunology
Source: <https://www.510kdatabase.net/k093908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX)
Date received	Dec 22, 2009
Decision date	Dec 1, 2010
Days to decision	344 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Euro-Diagnostica AB
Location	Malmö, SE
Contact	ROBERT SCHIFF
510(k) history	6 submissions · 6 cleared · 1997-2010

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