

K062045 EDIA ANTI-CCPDec 4, 2006
138 days to decisionK062045 · Product code: **NHX** · Immunology
Source: <https://www.510kdatabase.net/k062045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX)
Date received	Jul 19, 2006
Decision date	Dec 4, 2006
Days to decision	138 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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