

**K091657 IMMUNOSCAN CCPLUS**Nov 19, 2009  
163 days to decisionK091657 · Product code: **NHX** · Immunology  
Source: <https://www.510kdatabase.net/k091657/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX)
Date received	Jun 9, 2009
Decision date	Nov 19, 2009
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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