

**K052133 IMMUNOSCAN RA ANTI-CCP TEST SYSTEM**Dec 12, 2005  
129 days to decisionK052133 · Product code: **NHX** · Immunology  
Source: <https://www.510kdatabase.net/k052133/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX)
Date received	Aug 5, 2005
Decision date	Dec 12, 2005
Days to decision	129 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Eurodiagnostica</b>
Location	Frederick, MD, US
Contact	WILLIAM L BOTELER JR.
510(k) history	3 submissions · 3 cleared · 2005-2005

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