

**K061165 ELIA CCP, MODEL 14-5515-01**Aug 3, 2006  
99 days to decisionK061165 · Product code: **NHX** · Immunology  
Source: <https://www.510kdatabase.net/k061165/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX)
Date received	Apr 26, 2006
Decision date	Aug 3, 2006
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary
Other names	ELIA CCP CONTROL, MODEL 83-1009-01

**APPLICANT**

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Company	<b>Sweden Diagnostics (Us), Inc.</b>
Location	Portae, MI, US
Contact	MARTIN R MANN
510(k) history	1 submissions · 1 cleared · 2006-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061165/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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