

**K121576 IMMULITE 2000 ANTI-CCP IGG ASSAY**Apr 4, 2013  
309 days to decisionK121576 · Product code: **NHX** · Immunology  
Source: <https://www.510kdatabase.net/k121576/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX)
Date received	May 30, 2012
Decision date	Apr 4, 2013
Days to decision	309 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics, Inc.</b>
Location	New York, NY, US
Contact	SUSAN BROCCHI
Website	<a href="https://www.siemens-healthineers.com">https://www.siemens-healthineers.com</a>
510(k) history	152 submissions · 151 cleared · 2008-2026

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