

K070789 EUROIMMUN ANTI-CCP ELISADec 31, 2007
284 days to decisionK070789 · Product code: **NHX** · Immunology
Source: <https://www.510kdatabase.net/k070789/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Anti-cyclic Citrullinated Peptide (ccp) (NHX)
Date received	Mar 22, 2007
Decision date	Dec 31, 2007
Days to decision	284 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Euroimmun Us, LLC
Location	Boonton Twp, NJ, US
Contact	KATHRYN KOHL
510(k) history	6 submissions · 6 cleared · 2006-2007

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