

K112996 EUROIMMUN ANTI-ENA POOL ELISA (IGG)Apr 9, 2013
550 days to decisionK112996 · Product code: **LLL** · Immunology
Source: <https://www.510kdatabase.net/k112996/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Oct 7, 2011
Decision date	Apr 9, 2013
Days to decision	550 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Euroimmun US
Location	Morris Plains, NJ, US
Contact	KATHRYN KOHL
510(k) history	12 submissions · 11 cleared · 2012-2016

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