

K112221 EUROIMMUN ANTI-SLA/LP ELISA(LGG)Sep 11, 2012
406 days to decisionK112221 · Product code: **NIY** · Immunology
Source: <https://www.510kdatabase.net/k112221/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Anti-soluble Liver Antigen (sla), Autoimmune Hepatitis (NIY)
Date received	Aug 2, 2011
Decision date	Sep 11, 2012
Days to decision	406 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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