

**K113439 EUROIMMUN EUROLINE PROFILE AUTOIMMUNE  
LIVER DISEASE 8AG (IGG)**Apr 12, 2013  
508 days to decisionK113439 · Product code: **NIY** · Immunology  
Source: <https://www.510kdatabase.net/k113439/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Anti-soluble Liver Antigen (sla), Autoimmune Hepatitis (NIY)
Date received	Nov 21, 2011
Decision date	Apr 12, 2013
Days to decision	508 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113439/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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