

K140224 EUROIMMUN EUROLINE ENA PROFILE 9AG (IGG)Dec 9, 2014
314 days to decisionK140224 · Product code: **LKO** · Immunology
Source: <https://www.510kdatabase.net/k140224/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-rnp Antibody, Antigen And Control (LKO)
Date received	Jan 29, 2014
Decision date	Dec 9, 2014
Days to decision	314 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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