

K123261 EUROIMMUN ANTI-NRNP/SM ELISA (IGG)Jun 12, 2013
237 days to decisionK123261 · Product code: **LKO** · Immunology
Source: <https://www.510kdatabase.net/k123261/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-rnp Antibody, Antigen And Control (LKO)
Date received	Oct 18, 2012
Decision date	Jun 12, 2013
Days to decision	237 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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