

K131185 ANA SCREEN ELISA (IGG)Jul 15, 2013
80 days to decisionK131185 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k131185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Apr 26, 2013
Decision date	Jul 15, 2013
Days to decision	80 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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