

K140493 ELIA SCL-70S IMMUNOASSAYOct 30, 2014
245 days to decisionK140493 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k140493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Feb 27, 2014
Decision date	Oct 30, 2014
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Phadia GmbH
Location	Portae, MI, US
Contact	MARTIN R MANN
510(k) history	1 submissions · 1 cleared · 2014-2014

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