

**K072149 ELIA SYMPHONY IMMUNOASSAY, ANA CONTROL,
MODEL 14-55508-01,83-1004-01**Jan 15, 2008
165 days to decisionK072149 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k072149/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Aug 3, 2007
Decision date	Jan 15, 2008
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Phadia US, Inc.
Location	Portae, MI, US
Contact	MARTIN MANN
510(k) history	22 submissions · 21 cleared · 2006-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072149/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026