

**K993108 VARELISA RECOMBI ANA SCREEN EIA, MODELS 128
48/ 128 96**Nov 12, 1999
56 days to decisionK993108 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k993108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Sep 17, 1999
Decision date	Nov 12, 1999
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pharmacia & Upjohn Co.
Location	Westerville, OH, US
Contact	KAREN E MATIS
510(k) history	18 submissions · 18 cleared · 1996-2000

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