

K040810 VARELISA HISTONE ANTIBODIES, MODEL 16496May 14, 2004
46 days to decisionK040810 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k040810/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Mar 29, 2004
Decision date	May 14, 2004
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pharmacia Deutschland GmbH
Location	Freiburg, DE
Contact	MICHAEL LINSS
510(k) history	10 submissions · 10 cleared · 2002-2004

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