

K040811 VARELISA SSDNA ANTIBODIES, MODEL 14896May 13, 2004
45 days to decisionK040811 · Product code: **LRM** · Immunology
Source: <https://www.510kdatabase.net/k040811/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody (enzyme-labeled), Antigen, Control (LRM)
Date received	Mar 29, 2004
Decision date	May 13, 2004
Days to decision	45 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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