

**K040450 VARELISA B2 GLYCOPROTEIN I IGA ANTIBODIES,
MODELS 18948 AND 18996**May 11, 2004
81 days to decisionK040450 · Product code: **MSV** · Immunology
Source: <https://www.510kdatabase.net/k040450/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System,test,antibodies,b2 - Glycoprotein I (b2 - Gpi) (MSV)
Date received	Feb 20, 2004
Decision date	May 11, 2004
Days to decision	81 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040450/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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