

**K040452 VARELISA B2 GLYCOPROTEIN I ANTIBODIES  
SCREEN, MODELS 19048 AND 19096**May 11, 2004  
81 days to decisionK040452 · Product code: **MSV** · Immunology  
Source: <https://www.510kdatabase.net/k040452/>**SUBMISSION DETAILS**

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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**

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

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