

**K040451 VARELISA B2 GLYCOPROTEIN I IGM ANTIBODIES,  
MODELS 18848 AND 18896**May 11, 2004  
81 days to decisionK040451 · Product code: **MSV** · Immunology  
Source: <https://www.510kdatabase.net/k040451/>**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	<b>Pharmacia Deutschland GmbH</b>
Location	Freiburg, DE
Contact	MICHAEL LINSS
510(k) history	10 submissions · 10 cleared · 2002-2004

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040451/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026