

**K042629 VARELISA SM ANTIBODIES, MODEL 18296**Dec 8, 2004  
72 days to decisionK042629 · Product code: **LKP** · Immunology  
Source: <https://www.510kdatabase.net/k042629/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-sm Antibody, Antigen And Control (LKP)
Date received	Sep 27, 2004
Decision date	Dec 8, 2004
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sweden Diagnostics (Germany) GmbH</b>
Location	Freiburg, DE
Contact	SABINE KLUGBAUER
510(k) history	8 submissions · 8 cleared · 2004-2005

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