

**K041354 VARELISA GLIADIN IGA ANTIBODIES MODEL  
#19848/19896**Jul 16, 2004  
57 days to decisionK041354 · Product code: **MST** · Immunology  
Source: <https://www.510kdatabase.net/k041354/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antibodies, Gliadin (MST)
Date received	May 20, 2004
Decision date	Jul 16, 2004
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041354/> 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