

**K982433 REAADS IGM ANTI-B2GP1 TEST KIT**Dec 7, 1998  
146 days to decisionK982433 · Product code: **MSV** · Immunology  
Source: <https://www.510kdatabase.net/k982433/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System,test,antibodies,b2 - Glycoprotein I (b2 - Gpi) (MSV)
Date received	Jul 14, 1998
Decision date	Dec 7, 1998
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Corgenix, Inc.</b>
Location	Westminster, CO, US
Contact	NANCI DEXTER
510(k) history	23 submissions · 23 cleared · 1998-2008

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982433/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 25, 2026