

**K000920 REAADS IGA ANTI-PHOSPHATIDYLSERINE SEMI-  
QUANTITATIVE TEST KIT**Apr 26, 2000  
35 days to decisionK000920 · Product code: **MID** · Immunology  
Source: <https://www.510kdatabase.net/k000920/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Mar 22, 2000
Decision date	Apr 26, 2000
Days to decision	35 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/k000920/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 25, 2026