

**K946215 CARDIOLIPIN G EIA TEST SYSTEM**Jan 24, 1996  
399 days to decisionK946215 · Product code: **MID** · Immunology  
Source: <https://www.510kdatabase.net/k946215/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Dec 21, 1994
Decision date	Jan 24, 1996
Days to decision	399 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Hogan &amp; Hartson</b>
Location	Mchenry, IL, US
Contact	EDWARD C WILSON
510(k) history	26 submissions · 25 cleared · 1980-1998

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k946215/> 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 May 20, 2026