

**K920412 MODIFIED ORTHO EBV VCA-IGG ELISA**Jun 22, 1992  
143 days to decisionK920412 · Product code: **MCD** · Microbiology  
Source: <https://www.510kdatabase.net/k920412/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Ebv, Capsid (MCD)
Date received	Jan 31, 1992
Decision date	Jun 22, 1992
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Ortho Diagnostic Systems, Inc.</b>
Location	Carpinteria, CA, US
Contact	KIN W GRAY
510(k) history	126 submissions · 126 cleared · 1981-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k920412/> 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 14, 2026