

**K121046 STEROID 21-HYDROXYLASE ANTIBODY (21-OHAB)  
RIA ASSAY KIT**Dec 20, 2012  
258 days to decisionK121046 · Product code: **PCG** · Immunology  
Source: <https://www.510kdatabase.net/k121046/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	21-hydroxylase Antibody (21-ohab) (PCG)
Date received	Apr 6, 2012
Decision date	Dec 20, 2012
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Kronus Market Development Associates, Inc.</b>
Location	Boise, ID, US
Contact	HEATHER VIELE
510(k) history	11 submissions · 10 cleared · 2003-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121046/> 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 May 14, 2026