

**K092600 IMMULISA PR3 ANTIBODY ELISA**Oct 7, 2010  
409 days to decisionK092600 · Product code: **MOB** · Immunology  
Source: <https://www.510kdatabase.net/k092600/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Aug 24, 2009
Decision date	Oct 7, 2010
Days to decision	409 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Immco Diagnostics, Inc.</b>
Location	Buffalo, NY, US
Contact	KEVIN LAWSON
510(k) history	55 submissions · 55 cleared · 1988-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092600/> 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 30, 2026