

**K083615 EUROIMMUN ANTI BP 180-4X ELISA (IGG)**Mar 16, 2009  
98 days to decisionK083615 · Product code: **OEG** · Immunology  
Source: <https://www.510kdatabase.net/k083615/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Autoantibodies, Skin (bullous Pemphigoid 180 And Bullous Pemphigoid 230 (OEG)
Date received	Dec 8, 2008
Decision date	Mar 16, 2009
Days to decision	98 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Euroimmun Us, Inc.</b>
Location	Morristown, NJ, US
Contact	KATHRYN KOHL
510(k) history	19 submissions · 19 cleared · 2009-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083615/> 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 June 19, 2026