

**K153308 EUROIMMUN Anti-West Nile Virus ELISA (IgM)**Aug 12, 2016  
269 days to decisionK153308 · Product code: **NOP** · Microbiology  
Source: <https://www.510kdatabase.net/k153308/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elisa, Antibody, West Nile Virus (NOP)
Date received	Nov 17, 2015
Decision date	Aug 12, 2016
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153308/> 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