

**K061239 EUROIMMUN ANTI-HSV-2 ELISA (IGG) AND ANTI-HSV-1 ELISA (IGG) KIT**Jun 28, 2007  
421 days to decisionK061239 · Product code: MYF · Microbiology  
Source: <https://www.510kdatabase.net/k061239/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-2 (MYF)
Date received	May 3, 2006
Decision date	Jun 28, 2007
Days to decision	421 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Euroimmun Us, LLC</b>
Location	Boonton Twp, NJ, US
Contact	KATHRYN KOHL
510(k) history	6 submissions · 6 cleared · 2006-2007

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061239/> 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 June 26, 2026