

**K971596 EMIT II OPIATES 300/2000 ASSAY**Jun 25, 1997  
55 days to decisionK971596 · Product code: **DJG** · Toxicology  
Source: <https://www.510kdatabase.net/k971596/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	May 1, 1997
Decision date	Jun 25, 1997
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Behring Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	DAVID KOLESAR
510(k) history	145 submissions · 145 cleared · 1976-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971596/> 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 28, 2026