

**K921939 SERALYZER(R) THERAPEUTIC DRUG ASSAY  
CONTROL(ABNOR)**Jul 16, 1992  
83 days to decisionK921939 · Product code: **LAS** · Toxicology  
Source: <https://www.510kdatabase.net/k921939/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Specific Control Materials (LAS)
Date received	Apr 24, 1992
Decision date	Jul 16, 1992
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Heraeus Kulzer, Inc.</b>
Location	Elkhart, IN, US
Contact	ROSANNE M SAVOL
510(k) history	145 submissions · 145 cleared · 1988-2009

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k921939/> 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 May 20, 2026