

**K922043 ROCHE CALIBRATOR SERUM**Jun 16, 1992  
46 days to decisionK922043 · Product code: **JIX** · Chemistry  
Source: <https://www.510kdatabase.net/k922043/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	May 1, 1992
Decision date	Jun 16, 1992
Days to decision	46 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Roche Diagnostic Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	CAROL L KRIEGER
510(k) history	296 submissions · 296 cleared · 1983-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k922043/> 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 23, 2026