

**K930304 COBAS CORE FSH EIA**Sep 21, 1993  
243 days to decisionK930304 · Product code: **CGJ** · Chemistry  
Source: <https://www.510kdatabase.net/k930304/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Follicle-stimulating Hormone (CGJ)
Date received	Jan 21, 1993
Decision date	Sep 21, 1993
Days to decision	243 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/k930304/> 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