

K992981 ELECSYS ESTRADIOL CALSET IISep 24, 1999
21 days to decisionK992981 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k992981/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Sep 3, 1999
Decision date	Sep 24, 1999
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	PRISCILLA A HAMILL
510(k) history	264 submissions · 263 cleared · 1999-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992981/> 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 9, 2026