

K992890 ROCHE COBAS INTEGRA OPIATES 300/2000Nov 23, 1999
88 days to decisionK992890 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k992890/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Aug 27, 1999
Decision date	Nov 23, 1999
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992890/> 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