

**K991443 ROCHE COBAS INTEGRA SERUM BENZODIAZEPINES
(SBENZ)**Jun 22, 1999
57 days to decisionK991443 · Product code: **JXM** · Toxicology
Source: <https://www.510kdatabase.net/k991443/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Benzodiazepine (JXM)
Date received	Apr 26, 1999
Decision date	Jun 22, 1999
Days to decision	57 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991443/> 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