

**K963627 (MODIFIED VERSION) INTEGRA ION SELECTIVE
ELECTRODE (ISE) MODULE**Oct 24, 1996
43 days to decisionK963627 · Product code: **JGS** · Chemistry
Source: <https://www.510kdatabase.net/k963627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Sodium (JGS)
Date received	Sep 11, 1996
Decision date	Oct 24, 1996
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	RITA SMITH
510(k) history	296 submissions · 296 cleared · 1983-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k963627/>. 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 23, 2026