

K910305 GEM-PREMIER SYSTEMApr 3, 1991
69 days to decisionK910305 · Product code: **JGS** · Chemistry
Source: <https://www.510kdatabase.net/k910305/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Sodium (JGS)
Date received	Jan 24, 1991
Decision date	Apr 3, 1991
Days to decision	69 days
Third-party review	No

APPLICANT

Company	Mallinckrodt Sensor Systems, Inc.
Location	Ann Arbor, MI, US
Contact	BRUCE M BURGESS
510(k) history	2 submissions · 2 cleared · 1991-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k910305/>; 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 30, 2026