

**K091861 VITROS CHEMISTRY PRODUCTS NA + DT SLIDES,
MODEL 153 2290 AND DT CALIBRATOR KIT, MODEL 195 7927**

Sep 3, 2009
76 days to decision

K091861 · Product code: **JGS** · Chemistry
Source: <https://www.510kdatabase.net/k091861/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Ion Specific, Sodium (JGS)
Date received	Jun 19, 2009
Decision date	Sep 3, 2009
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	MARLENE A HANNA
510(k) history	106 submissions · 104 cleared · 1997-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k091861/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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