

K081411 VITROS CHEMISTRY PRODUCT NA+ SLIDESJun 30, 2008
41 days to decisionK081411 · Product code: **JGS** · Chemistry
Source: <https://www.510kdatabase.net/k081411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Ion Specific, Sodium (JGS)
Date received	May 20, 2008
Decision date	Jun 30, 2008
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary
Other names	VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 2

APPLICANT

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

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