

K160225 GEM Premier 5000 (Measured Parameters:Sodium, Potassium, Chloride, Ionized Calcium), GEM CVP 5 tBili, GEM System Evaluator, GEM Hematocrit EvaluatorDec 14, 2016
320 days to decisionK160225 · Product code: **JGS** · Chemistry
Source: <https://www.510kdatabase.net/k160225/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Sodium (JGS)
Date received	Jan 29, 2016
Decision date	Dec 14, 2016
Days to decision	320 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Instrumentation Laboratory CO
Location	Mchenry, IL, US
Contact	CAROL MARBLE
510(k) history	321 submissions · 320 cleared · 1976-2023

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