

K110212 INRATIO2 PI/NR MONITORING SYSTEMMay 1, 2012
462 days to decisionK110212 · Product code: **GJS** · Hematology
Source: <https://www.510kdatabase.net/k110212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Test, Time, Prothrombin (GJS)
Date received	Jan 25, 2011
Decision date	May 1, 2012
Days to decision	462 days
Third-party review	No
Summary / Statement	Summary
Other names	INRATIO PT/INR TEST STRIP

APPLICANT

Company	Alere San Diego, Inc (Formally Biosite Incorporate
Location	San Deigo, CA, US
Contact	MARA CALER
510(k) history	1 submissions · 0 cleared · 2012-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110212/> 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 14, 2026