FDA 510(k) Premarket Notification

K110212 INRATIO2 PI/NR MONITORING SYSTEM

CLEARED

May 1, 2012
462 days to decision

K110212 · 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