

K102908 NOFACT IXDec 19, 2011
444 days to decisionK102908 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k102908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Oct 1, 2010
Decision date	Dec 19, 2011
Days to decision	444 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	R2 Diagnostics, Inc.
Location	South Bend, IN, US
Contact	MARC D GOLDFORD
510(k) history	10 submissions · 10 cleared · 2004-2011

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