

K102851 NOFACT VIIIDec 19, 2011
446 days to decisionK102851 · Product code: **GJT** · Hematology
Source: <https://www.510kdatabase.net/k102851/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Factor Deficient (GJT)
Date received	Sep 29, 2010
Decision date	Dec 19, 2011
Days to decision	446 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102851/> 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 15, 2026