

K050817 T-TEKDec 12, 2005
256 days to decisionK050817 · Product code: **GJA** · Hematology
Source: <https://www.510kdatabase.net/k050817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Thrombin Time (GJA)
Date received	Mar 31, 2005
Decision date	Dec 12, 2005
Days to decision	256 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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