

K082631 THROMBO TEK PSE, MODEL 90-480Dec 17, 2008
98 days to decisionK082631 · Product code: **GGP** · Hematology
Source: <https://www.510kdatabase.net/k082631/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Sep 10, 2008
Decision date	Dec 17, 2008
Days to decision	98 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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