

K010158 THROMBOMAX-HS WITH CALCIUM, MODEL T6540Mar 22, 2001
64 days to decisionK010158 · Product code: **GGO** · Hematology
Source: <https://www.510kdatabase.net/k010158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Thromboplastin And Control (GGO)
Date received	Jan 17, 2001
Decision date	Mar 22, 2001
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT II
510(k) history	164 submissions · 164 cleared · 1984-2002

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