

K161316 George King Coumadin PlasmaFeb 23, 2017
288 days to decisionK161316 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k161316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	May 11, 2016
Decision date	Feb 23, 2017
Days to decision	288 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	George King Bio-Medical, Inc.
Location	Overland Park, KS, US
Contact	BARBARA YOUNG
510(k) history	5 submissions · 5 cleared · 1995-2017

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