

**K162705 VALIDATE® D-Dimer Calibration Verification/ Linearity
Test Kit**Jan 5, 2017
99 days to decisionK162705 · Product code: **GGN** · Hematology
Source: <https://www.510kdatabase.net/k162705/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Sep 28, 2016
Decision date	Jan 5, 2017
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Maine Standards Company, LLC
Location	Windham, ME, US
Contact	JAMES CHAMPLIN
510(k) history	7 submissions · 7 cleared · 2011-2017

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