

**K163498 VALIDATE Heparin Calibration Verification/Linearity  
Test Kit**Mar 16, 2017  
93 days to decisionK163498 · Product code: **GGN** · Hematology  
Source: <https://www.510kdatabase.net/k163498/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plasma, Coagulation Control (GGN)
Date received	Dec 13, 2016
Decision date	Mar 16, 2017
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163498/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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