

**K183160 TEG 6s Hemostasis System, TEG 6s Citrated: K, RT, FF Assay Cartridge**May 9, 2019  
175 days to decisionK183160 · Product code: JPA · Hematology  
Source: <https://www.510kdatabase.net/k183160/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Nov 15, 2018
Decision date	May 9, 2019
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Haemonetics Corporation</b>
Location	Braintree, MA, US
Contact	Nancy Bengtson
Website	<a href="http://www.haemonetics.com/">http://www.haemonetics.com/</a>
510(k) history	7 submissions · 7 cleared · 2016-2025

Haemonetics Corporation provides innovative medical technology solutions that improve the quality, effectiveness and efficiency of care. The company serves hospitals, plasma centers, and blood centers with a comprehensive suite of products. Haemonetics operates with a manufacturing facility in Braintree, US. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2016. Haemonetics specializes in hematology devices and blood management technologies, with recent cleared devices spanning hemostasis testing systems and autotransfusio...

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