

K160502 TEG 6s Hemostasis SystemApr 19, 2017
421 days to decisionK160502 · Product code: **JPA** · Hematology
Source: <https://www.510kdatabase.net/k160502/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Feb 23, 2016
Decision date	Apr 19, 2017
Days to decision	421 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Haemonetics Corporation
Location	Braintree, MA, US
Contact	Paige Sweeney
Website	http://www.haemonetics.com/
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...
