

K243858 TEG 6s Hemostasis System Citrated: K, KH, RT, FF Assay Cartridge

Jan 15, 2025
30 days to decisionK243858 · Product code: JPA · Hematology
Source: <https://www.510kdatabase.net/k243858/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Dec 16, 2024
Decision date	Jan 15, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Haemonetics Corporation
Location	Braintree, MA, US
Contact	Erica Molaro
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...