FDA 510(k) Premarket Notification

K232018 Citrated: K, KH, RTH, FFH

CLEARED

Mar 29, 2024
266 days to decision

K232018 · Product code: **JPA** · Hematology
Source: https://www.510kdatabase.net/k232018/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Multipurpose For In Vitro Coagulation Studies (JPA)
Date received	Jul 7, 2023
Decision date	Mar 29, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Haemonetics Corporation**
Location	Braintree, MA, US
Contact	Julie Ewend
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...