

K221722 Haemonetics Cell Saver Elite/Elite+ Autotransfusion System (CSE-E-US/CSE-EW-US)

Nov 15, 2022
154 days to decisionK221722 · Product code: CAC · Cardiovascular
Source: <https://www.510kdatabase.net/k221722/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Autotransfusion (CAC)
Date received	Jun 14, 2022
Decision date	Nov 15, 2022
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Haemonetics Corporation
Location	Braintree, MA, US
Contact	Ergang Alexis
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...