

# K162423 Haemonetics Cell Saver Elite/Elite+ Autotransfusion System

Jan 3, 2017  
126 days to decisionK162423 · Product code: **CAC** · Anesthesiology  
Source: <https://www.510kdatabase.net/k162423/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Autotransfusion (CAC)
Date received	Aug 30, 2016
Decision date	Jan 3, 2017
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Haemonetics Corporation</b>
Location	Braintree, MA, US
Contact	MARK ANZALONE
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k162423/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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