

**K043127 HAEMONETICS CARDIOVASCULAR PERIOPERATIVE
AUTOTRANSFUSION SYSTEM**Jan 4, 2005
53 days to decisionK043127 · Product code: **CAC** · Anesthesiology
Source: <https://www.510kdatabase.net/k043127/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Autotransfusion (CAC)
Date received	Nov 12, 2004
Decision date	Jan 4, 2005
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Haemonetics Corp.
Location	Mchenry, IL, US
Contact	GABRIEL J MURACA
Website	http://www.haemonetics.com/
510(k) history	28 submissions · 28 cleared · 1980-2012

Haemonetics Corp. is a global provider of blood and plasma supplies and services. Founded in the 1970s, the company expanded to offices in 16 countries and serves markets across Asia, Europe, and the Americas. The company has received FDA 510(k) clearances from total submissions between 1980 and 2012. Anesthesiology devices represent the dominant category, including autotransfusion systems and blood recovery technologies. This regulatory record reflects the company's historical focus on perioperative blood management solutions. Notable cleared devices include the ORTHOPAT...