

K052626 SMARTSUCTION HARMONY DEVICEOct 5, 2005
12 days to decisionK052626 · Product code: **BTA** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k052626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Portable, Aspiration (manual Or Powered) (BTA)
Date received	Sep 23, 2005
Decision date	Oct 5, 2005
Days to decision	12 days
Third-party review	Yes
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...
