

K852645 FLUID MANAGEMENT SYSTEMDec 9, 1985
171 days to decisionK852645 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k852645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Jun 21, 1985
Decision date	Dec 9, 1985
Days to decision	171 days
Third-party review	No

APPLICANT

Company	Haemonetics Corp.
Location	Mchenry, IL, US
Contact	PAUL H PATRONE
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...
