

K810365 HAEMONETICS 170 Y INFUSION SETMar 31, 1981
47 days to decisionK810365 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k810365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Feb 12, 1981
Decision date	Mar 31, 1981
Days to decision	47 days
Third-party review	No

APPLICANT

Company	Haemonetics Corp.
Location	Mchenry, IL, US
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...