FDA 510(k) Premarket Notification

K800358 Y-TYPE INFUSION SET (2 LEAD)

CLEARED

Apr 16, 1980
56 days to decision

K800358 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k800358/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Feb 20, 1980
Decision date	Apr 16, 1980
Days to decision	56 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...