

**K860969 FLUID MANAGEMENT SYSTEM (MODIFIED)**May 6, 1986  
56 days to decisionK860969 · Product code: **FRN** · General Hospital  
Source: <https://www.510kdatabase.net/k860969/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Pump, Infusion (FRN)               |
| Date received         | Mar 11, 1986                       |
| Decision date         | May 6, 1986                        |
| Days to decision      | 56 days                            |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Haemonetics Corp.</b>  |
| Location       | Mchenry, IL, US   |
| Contact        | PAUL H PATRONE  |
| Website        | <a href="http://www.haemonetics.com/">http://www.haemonetics.com/</a> |
| 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...

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