

**K953681 HAEMONETICS THERAPEUTIC PLASMA EXCHANGE SET**Jun 4, 1996  
302 days to decisionK953681 · Product code: **LKN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k953681/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Separator, Automated, Blood Cell And Plasma, Therapeutic (LKN)
Date received	Aug 7, 1995
Decision date	Jun 4, 1996
Days to decision	302 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Haemonetics Corp.</b>
Location	Mchenry, IL, US
Contact	ALICIA R LOPEZ
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...