

K160197 Haemonetics Cell Saver Elite Autotransfusion SystemMay 24, 2016
118 days to decisionK160197 · Product code: **CAC** · Anesthesiology
Source: <https://www.510kdatabase.net/k160197/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Apparatus, Autotransfusion (CAC) |
| Date received | Jan 27, 2016 |
| Decision date | May 24, 2016 |
| Days to decision | 118 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Haemonetics Corporation |
| Location | Braintree, MA, US |
| Contact | Mark Anzalone |
| Website | http://www.haemonetics.com/ |
| 510(k) history | 7 submissions · 7 cleared · 2016-2025 |

Haemonetics Corporation provides innovative medical technology solutions that improve the quality, effectiveness and efficiency of care. The company serves hospitals, plasma centers, and blood centers with a comprehensive suite of products. Haemonetics operates with a manufacturing facility in Braintree, US. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2016. Haemonetics specializes in hematology devices and blood management technologies, with recent cleared devices spanning hemostasis testing systems and autotransfusio...
