

**K192368 CATSmart**Sep 27, 2019  
28 days to decisionK192368 · Product code: **CAC** · Cardiovascular  
Source: <https://www.510kdatabase.net/k192368/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Autotransfusion (CAC)
Date received	Aug 30, 2019
Decision date	Sep 27, 2019
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fresenius Kabi AG</b>
Location	Lake Zurich, IL, US
Contact	Shane Sawall
Website	<a href="http://www.fresenius-kabi.com/">http://www.fresenius-kabi.com/</a>
510(k) history	12 submissions · 12 cleared · 2013-2026

Fresenius Kabi AG is a global healthcare company specializing in infusion therapy, IV drugs, and medical devices. The company operates with a manufacturing facility in Lake Zurich, Illinois, and serves hospitals and healthcare systems worldwide. Fresenius Kabi has received FDA 510(k) clearances from total submissions since 2013. The company's regulatory portfolio focuses on infusion systems, administration sets, and blood processing technologies for general hospital and cardiovascular applications. The latest clearance in 2026 demonstrates continued innovation and active ...

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