

K160735 CATSmartSep 16, 2016
183 days to decisionK160735 · Product code: **CAC** · Anesthesiology
Source: <https://www.510kdatabase.net/k160735/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Autotransfusion (CAC)
Date received	Mar 17, 2016
Decision date	Sep 16, 2016
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Kabi AG
Location	Lake Zurich, IL, US
Contact	Barry G. Hicks
Website	http://www.fresenius-kabi.com/
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 ...
