FDA 510(k) Premarket Notification

K180831 CATSmart

CLEARED

Dec 10, 2018
255 days to decision

K180831 · Product code: **CAC** · Cardiovascular
Source: https://www.510kdatabase.net/k180831/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Autotransfusion (CAC)
Date received	Mar 30, 2018
Decision date	Dec 10, 2018
Days to decision	255 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 ...