FDA 510(k) Premarket Notification

CLEARED

K210089 CATSmart, Automated Blood Processing Autotransfusion System

Feb 11, 2021
29 days to decision

K210089 · Product code: **CAC** · Cardiovascular
Source: https://www.510kdatabase.net/k210089/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Autotransfusion (CAC)
Date received	Jan 13, 2021
Decision date	Feb 11, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fresenius Kabi AG**
Location	Lake Zurich, IL, US
Contact	Deepak Mehta
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 ...

REGULATORY CONSULTANT

Consulting firm	**Fresenius Kabi**
Contact	Cheryl Chamberlain Roscher

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov