FDA 510(k) Premarket Notification

K200530 AMICUS Separator System

CLEARED

Sep 11, 2020
193 days to decision

K200530 · Product code: **GKT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k200530/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Separator, Automated, Blood Cell, Diagnostic (GKT)
Date received	Mar 2, 2020
Decision date	Sep 11, 2020
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fresenius Kabi AG**
Location	Lake Zurich, IL, US
Contact	Kim Forch
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 ...