

K180615 AMICUS Separator System, AMICUS Exchange Kit - Therapeutics, Waste Transfer Set, Blood Component Filter Set With Vented Spike and Luer Adapter

Dec 4, 2018
271 days to decision

K180615 · Product code: **LKN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k180615/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Separator, Automated, Blood Cell And Plasma, Therapeutic (LKN)
Date received	Mar 8, 2018
Decision date	Dec 4, 2018
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fresenius Kabi USA,Llc
Location	Lake Zurich, IL, US
Contact	Kim Forch
510(k) history	2 submissions · 2 cleared · 2016-2018

CLINICAL EVIDENCE - NCT02372877

Evaluation of the AMICUS RBCx System in Sickle Cell Patients

Status	Completed
Enrollment	83 patients (actual)
Study sites	6 sites
Condition studied	Sickle Cell Anemia
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jan 19, 2018
Sponsor	Fenwal, Inc. (Industry)

Primary outcome

Actual Fraction of Original Red Blood Cells Remaining to the Target Fraction of Cells Remaining (FCR).

Secondary outcome

Accuracy of Patient's End Hematocrit as Measured by the Patient's Post-procedure Hematocrit.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02372877