

K162462 AMICUS Separator System, AMICUS Separator SystemNov 23, 2016
82 days to decisionK162462 · Product code: **GKT** · Hematology
Source: <https://www.510kdatabase.net/k162462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Separator, Automated, Blood Cell, Diagnostic (GKT)
Date received	Sep 2, 2016
Decision date	Nov 23, 2016
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary
Other names	Refurbished

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162462/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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