

**K111702 AMICUS SEPARATOR SYSTEM- USE IN
THERAPEUTIC PLASMA EXCHANGE AND FILTER SET FOR
AMICUS TPE**Mar 22, 2012
279 days to decisionK111702 · Product code: **LKN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k111702/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Separator, Automated, Blood Cell And Plasma, Therapeutic (LKN)
Date received	Jun 17, 2011
Decision date	Mar 22, 2012
Days to decision	279 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fenwal, Inc.
Location	Lake Zurich, IL, US
Contact	Kim Forch
510(k) history	3 submissions · 3 cleared · 2008-2014

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