

K153601 Spectra Optia Apheresis SystemJan 14, 2016
29 days to decisionK153601 · Product code: **LKN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k153601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Separator, Automated, Blood Cell And Plasma, Therapeutic (LKN)
Date received	Dec 16, 2015
Decision date	Jan 14, 2016
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumobct, Inc.
Location	Lakewood, CO, US
Contact	Nicholas Wong
510(k) history	8 submissions · 8 cleared · 2013-2019

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