

K181049 Spectra Optia Apheresis SystemNov 1, 2018
195 days to decisionK181049 · Product code: **LKN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k181049/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Separator, Automated, Blood Cell And Plasma, Therapeutic (LKN)
Date received	Apr 20, 2018
Decision date	Nov 1, 2018
Days to decision	195 days
Third-party review	No
Combination product	No
PCCP authorized	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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