

K183081 Spectra Optia Apheresis SystemFeb 5, 2019
91 days to decisionK183081 · Product code: **LKN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k183081/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Separator, Automated, Blood Cell And Plasma, Therapeutic (LKN)
Date received	Nov 6, 2018
Decision date	Feb 5, 2019
Days to decision	91 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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