

**K172590 Spectra Optia Apheresis System**Mar 2, 2018  
185 days to decisionK172590 · Product code: **LKN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k172590/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Separator, Automated, Blood Cell And Plasma, Therapeutic (LKN)
Date received	Aug 29, 2017
Decision date	Mar 2, 2018
Days to decision	185 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172590/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026