

**K151368 Spectra Optia Apheresis System, Spectra Optia Exchange Set (with AC Connection), Spectra Optia AC Connection Adapter**

Sep 11, 2015  
113 days to decision

K151368 · Product code: **LKN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k151368/>

**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	May 21, 2015
Decision date	Sep 11, 2015
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terumo Bct</b>
Location	Lakewood, CO, US
Contact	Nicholas Wong
510(k) history	1 submissions · 1 cleared · 2015-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k151368/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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