

K132429 SPECTRA OPTIA APHERESIS SYSTEM, SPECTRA OPTIA SYSTEM SOFTWARE, SPECTRA OPTIA EXCHANGE DISPOSABLE SET

Dec 6, 2013
123 days to decision

K132429 · Product code: **LKN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k132429/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Separator, Automated, Blood Cell And Plasma, Therapeutic (LKN)
Date received	Aug 5, 2013
Decision date	Dec 6, 2013
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumobct, Inc.
Location	Lakewood, CO, US
Contact	TINA O'BRIEN
510(k) history	8 submissions · 8 cleared · 2013-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k132429/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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