

K141938 SPECTRA OPTIA APHERESIS SYSTEM, SPECTRA OPTIA EXCHANGE SET (DISPOSABLE BLOOD TUBING SET)

Mar 23, 2015
249 days to decision

K141938 · Product code: **LKN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k141938/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Separator, Automated, Blood Cell And Plasma, Therapeutic (LKN)
Date received	Jul 17, 2014
Decision date	Mar 23, 2015
Days to decision	249 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumobct, Inc.
Location	Lakewood, CO, US
Contact	PATTI ARNDT
510(k) history	8 submissions · 8 cleared · 2013-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k141938/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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