

K131744 SPECTRA OPTIA APHERESIS SYSTEM, SPECTRA OPTIA SINGLE-NEEDLE CONNECTOR, SPECTRA OPTIA SYSTEM SOFTWARE

Aug 8, 2013
56 days to decision

K131744 · Product code: **LKN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k131744/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Separator, Automated, Blood Cell And Plasma, Therapeutic (LKN)
Date received	Jun 13, 2013
Decision date	Aug 8, 2013
Days to decision	56 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/k131744/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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