

# Terumo Advanced Perfusion System 1 News

Mar 14, 2024 · 510 (k) Number: BK231035 Applicant: Terumo BCT Device Name: Rika Plasma Donation System (V2.1) Decision Date: 3/7/2024 Supporting Documents BK231035 Letter ... The legally marketed device to which substantial equivalence is claimed is: K140516 - Terumo Pen Injector Needle 34, manufactured by Kofu Factory of Terumo Corporation. Mar 14, 2024 · Terumo BCT conducted a prospective, open-label, multi-center study to ensure the collection volume of plasma collected with the Rika Plasma Donation system met the individualized ... 510 (k) Number: BK230843 Applicant: Terumo BCT Device Name: Reveos® Automated Whole Blood Processing System Decision Date: 7/27/2023 Supporting Documents BK230843 Letter BK230843 ... You can search the releasable 510(k) database by Panel, 510(k) number, Product code or Device name. A search query will produce information from the database in the following format: Nov 7, 2024 · Applicant: Terumo BCT, Inc. Device Name: Rika Plasma Donation System (42000) Decision Date: 11/5/2024 Supporting Documents BK241097 Letter BK241097 Summary Content ... July 2, 2025 Terumo Cardiovascular Systems THI Plant Rahul Reddy Chinkeri Senior Regulatory Affairs Specialist 6190 Jackson Rd Ann Arbor, Michigan 48103 May 4, 2026 · 510 (k) Premarket Notification FDA Home Medical Devices Databases Device Prococode: QSK Applicant's Name and Address: Terumo Aortic (Vascutek Ltd) Newmains Avenue, Inchinnan Renfrewshire, PA4 9RR Scotland, UK Date(s) of Panel Recommendation: None Premarket... Terumo Corporation c/o Patrick McDonald Senior Regulatory Affairs Specialist Terumo Medical Corporation 265 Davidson Avenue, Suite 320 Somerset, New Jersey 08873

## **BK231035 - Rika Plasma Donation System (V2.1) | FDA**

*510 (k) Premarket Notification - Food and Drug Administration*

*SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)*

*BK241097 - Rika Plasma Donation System (42000) | FDA*

## **BK230843 - Reveos Automated Whole Blood Processing System**

[Search the Releasable 510 \(k\) Database | FDA](#)

[BK231035 Summary - U.S. Food and Drug Administration](#)

**November 21, 2025 Terumo Corporation Regulatory Affairs ...**

*Terumo Cardiovascular Systems THI Plant Rahul Reddy Chinkeri ...*

**Patrick McDonald Terumo Medical Corporation 265 Davidson ...**

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