BK210635 - 510(k) Summary

I. SUBMITTER

Terumo BCT, Inc.
10811 W. Collins Avenue
Lakewood, Colorado 80215
Phone: 720-480-6702

Contact Person: Ashley Davis
Title: Sr. Specialist, Regulatory Affairs
Phone: 303-542-5494
Fax: 303-231-4756

Date Prepared: September 22, 2021

II. DEVICE

Trade Name of Device:	Rika Plasma Donation System
Common or Usual Name:	Automated Blood Collection System, or Separator, Automated, Blood Cell, Diagnostic/ Automated Blood Cell Separator
Classification Name:	Separator, Automated, Blood Cell, Diagnostic
Regulatory Number:	21 CFR 864.9245(b)
Product Code:	GKT

III. PREDICATE DEVICE

Table 1: Predicate and Reference Device Information

Device	Product Classification	Trade Name	Manufacturer and 510(k) Holder	510(k) Clearance Number
Predicate	GKT	Trima Accel® Automated Blood Collection System	Terumo BCT, Inc.	BK170157
Reference	GKT	Haemonetics PCS®2 Plasma Collection System	Haemonetics Corporation	BK150292

IV. DEVICE DESCRIPTION

A. Device Identification

Table 2: Device Identification

Product Name	Catalog Number
Rika Plasma Donation system	42000

Rika Plasma Separation Set	21200
Rika Plasma Bottle	21300

B. Device Characteristics

The Rika Plasma Donation System is an automated blood component collection system that uses centrifugal force to separate whole blood into plasma and its remaining cells. The plasma is collected, and the remaining cells and saline, if configured, are returned to the donor.

C. Device Description

The Rika Plasma Donation System is an automated plasma donation system and is comprised of four major subsystems: 1) Rika Plasma Donation system, 2) embedded software, 3) Rika Plasma Separation Set, and 4) Rika Plasma Bottle. Each of the four subsystems work together to complete a source plasma collection from the donor.

D. Environment of Use

The operation of the Rika Plasma Donation System is performed by trained operators in a blood center or source plasma donation centers. Operators are commonly trained on the principles of apheresis by their organization. Operators of the device have a variety of backgrounds and professional training, and the primary users are expected to be donation technicians, phlebotomists, and laboratory technicians.

E. Key Performance Specifications/Characteristics of the Device

The Rika Plasma Donation System uses centrifugal force to separate whole blood into plasma and the remaining cells. The plasma is collected, and the remaining cells and saline, if configured, are returned to the donor.

V. INTENDED USE

The intended use for the Rika Plasma Donation System is to collect source plasma from healthy donors.

VI. INDICATIONS FOR USE

The Indication for Use statement for the Rika Plasma Donation System is as follows:

> The Rika Plasma Donation System is an automated blood cell separator device and singleuse sterile disposable set intended for use in collecting source plasma with or without saline compensation.

The Indications for Use statement is not identical to predicate device or reference device, because the indications for use for the Rika Plasma Donation System is narrower than that of the predicate and reference devices. The predicate and reference devices also have indications to collect products beyond source plasma. The differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate or reference devices.

VII. TECHNOLOGICAL COMPARISON

Provided in **Table 3** is a high-level comparison of the Rika Plasma Donation System to the predicate and reference devices.

Table 3: Device Comparison Table

Category	Subject Device	Predicate Device	Reference Device	Comparison
Indication for Use	Collection of Source Plasma	Collection of Red Blood Cells, Platelets, Plasma for Transfusion and Source Plasma	Collection of Source Plasma and Plasma for Transfusion	Similar – Subject Device is only for collection of plasma, which is narrower than the predicate and reference devices
Fundamental Scientific Technology	Channel based centrifugal separation	Channel based centrifugal separation	Blow-molded bowl centrifugal separation	Similar – all use centrifugal separation. Subject and Predicate use channel based technology
Hardware	Electro-mechanical device	Electro-mechanical device	Electro-mechanical device	Similar – all are electro-mechanical devices, but the exact parts used are different among the three devices.
Software	Embedded + Protocol	Embedded that is configurable for country of use	Embedded	Similar – software for all three devices allows for collection of source plasma following regulatory requirements. Implementation differences are based on device design.
Disposable Tubing Set	Open set utilizing a separation set and separate bottle	Functionally closed set with integrated separation set and plasma storage bags	Open set utilizing a disposable set and separate bottle	Similar – the differences do not impact the safety or effectiveness of the device.
Sterilization	Separation Set – EO Bottle – radiation SAL $\leq 1.0 \times 10^{-6}$	Disposable Set – EO SAL $\leq 1.0 \times 10^{-6}$	Disposable Set – EO Bottle – radiation SAL $\leq 1.0 \times 10^{-6}$	Similar – the differences do not impact the safety or effectiveness of the device.
Shelf Life	Separation Set – 1year Bottle – 1-year	Disposable Set – 2 years	Disposable Set – 2 years	Similar – the differences do not impact the safety or effectiveness of the device.

Table 3: Device Comparison Table

Category	Subject Device	Predicate Device	Reference Device	Comparison

Collection Accuracy	±3g of the target volume	±10% of the display value	±5g	The differences do not impact the safety or effectiveness of the device.

VIII. PERFORMANCE DATA

The following types of data were provided in support of the substantial equivalence determination. Each type of data is further expanded upon in the sections below.

- Performance Testing
- Biocompatibility Testing
- Electrical Safety and Electromagnetic Compatibility Testing
- Software Testing
- Sterility Testing
- Shelf Life Testing
- Clinical Testing

A. Performance Testing

The Rika Plasma Donation System was tested against its performance requirements and user needs through demonstration and direct testing. The testing showed that The Rika Plasma Donation System performed according to its performance requirements, met its user needs and is usable by the intended users.

B. Biocompatibility Testing

The Rika Plasma Separation Set and Rika Plasma Bottle have been evaluated for biocompatibility and are considered biocompatible per their intended use. The Rika Plasma Separation Set and Rika Plasma Bottle comply with ISO 10993-1:2018.

C. Electrical Safety and Electromagnetic Compatibility (EMC) Testing

Electrical safety and EMC testing were conducted on the Rika Plasma Donation system. The Rika Plasma Donation system complies with IEC 60601-1:2005/AMD1:2012/AMD2:2020, IEC 60601-1-8:2006/AMD1:2012/AMD2:2020, and IEC 60601-1-2:2014/A1:2020.

D. Software Testing

Software testing was conducted, and documentation was provided as recommended for a “major” level of concern software by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

E. Sterility Testing

The Rika Plasma Separation Set is sterilized by Ethylene Oxide. The sterilization cycle was validated in accordance with ANSI/AAMI/ISO 11135:2014 and the sterility assurance level is $\leq 1.0 \times 10^{-6}$.

The Rika Plasma Bottle is sterilized using e-beam radiation. The sterilization dose was validated using the VDmax approach as described in ANSI/AAMI/ISO TIR 13004:2013 which expands on the VDmax methods listed in ANSI/AAMI/ISO 11137-2:2013 and the sterility assurance level is $\leq 1.0 \times 10^{-6}$.

F. Shelf Life Testing

The shelf life for both the Rika Plasma Separation Set and Rika Plasma Bottle is 1-year.

G. Clinical Studies

Clinical testing of the Rika Plasma Donation System included a device performance study that included 142 healthy donors. Substantial equivalence was based in part on the clinical study.

Device Performance Study

The device performance study was a prospective, open label, multi-center study to ensure the collection weight of plasma collected meets the US FDA nomogram for automated collection of source plasma.

Location of Study

The study was conducted under IDE 27242 at locations within the United States only.

Primary endpoint

The primary endpoint was proportion of plasma units with an acceptable collection weight as determined by the USA FDA Nomogram. An acceptable collection weight was defined as device collection accuracy of ±3g of the plasma target. To ensure the full range of the US FDA nomogram was tested, sites aimed to collect 20% of the plasma donations in the lower weight range, 20% in the middle weight range, and 60% in the higher weight range per the Clinical Investigation Plan. **Table 4** summarizes the results of the study.

Table 4: Primary Endpoint Details

Parameter	Participant Weight Category			Overall
	110lb – 149lb	150lb-174lb	≥175lb	
Reported Plasma Collection Weight (g)				
n	23	26	75	124
Target	705	845	900	-
Mean (SD)	705.0 (0.00)	845.0 (0.20)	899.9 (0.31)	852.2 (73.82)
Median	705.0	845.0	900.0	900.0
Min, Max	705, 705	844, 845	899, 900	705, 900
Plasma Collection Weight ±3 Grams of Target Weight, n (%)				
Yes	23 (100.0)	26 (100.0)	75 (100.0)	124 (100.0)
No	0	0	0	0

Safety

No safety signals were observed in this study. All reported Procedure-Emergent Adverse Events (PEAEs) were anticipated and have been previously reported as potential AEs during apheresis donation as indicated in the Clinical Investigation Plan and Informed Consent Form. There were no device-related PEAEs or unanticipated adverse device effects (UADEs) reported during this study.

Patient Accountability

Table 5: Patient Accountability

Stage	Overall
Enrollment	*142*

Lead-In Participants	*3*
Regular Participants	*139*
Procedure Not Initiated	*4*
Procedure Initiated (safety set)	*138*
Non-Evaluable Product Collected	*14*
Evaluable Product Collected (Evaluable Analysis Set)	*124*

Summary

Based on the clinical performance as documented in the device performance study, the Rika Plasma Donation System was found to meet the US FDA nomogram for automated collection of source plasma and has a safety profile that is similar to the predicate device.

IX. CONCLUSIONS

Based on the results of the non-clinical and clinical tests performed on the Rika Plasma Donation System, it is as safe and effective as the legally marketed predicate and reference devices. The information provided in the 510(k) demonstrates that the Rika Plasma Donation System is substantially equivalent to the identified predicate and reference devices.