510(k) Summary

I. SUBMITTER

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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. DEVICE CHARACTERISTICS SUMMARY

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. When the Rika Plasma Donation System utilizes the individualized nomogram, it uses a donor's characteristics to determine the amount of plasma to collect.

IV. 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 single-use sterile disposable set intended for use in collecting source plasma with or without saline compensation.

V. TECHNOLOGICAL COMPARISON

Provided in **Table 1** is a high-level comparison of the Rika Plasma Donation System utilizing the individualized nomogram to the predicate and reference devices.

Table 1: Device Comparison Table

Category	Subject Device	Predicate Device	Reference Device	Comparison
Device Name	**Rika Plasma Donation System**	**Terumo BCT: Rika Plasma Donation System**	**Haemonetics: NexSys PCS® Plasma Collection System with Persona®**	N/A
Classification Name	Automated blood cell separator	Automated blood cell separator	Automated blood cell separator	Same
Regulatory Number	21 CFR Part 864.9245	21 CFR Part 864.9245	21 CFR Part 864.9245	Same
Product Code	GKT	GKT	GKT	Same
Class	II	II	II	Same
Indication for Use	Collection of Source Plasma	Collection of Source Plasma	Collection of Source Plasma and Plasma for Transfusion	Similar
Fundamental Scientific Technology	Channel based centrifugal separation	Channel based centrifugal separation	Blow-molded bowl centrifugal separation	Similar
Collection Nomograms	Plasma Volume Collection Volume Individualized	Plasma Volume Collection Volume	Plasma Volume Collection Volume Persona	Similar
Software	Embedded + Protocol	Embedded + Protocol	Embedded	Similar
Max Plasma Volume Limits	1000 mL	1992 Nomogram Limits	1000 mL	Similar
AC Ratio	1:16	1:16	1:16	Same

VI. 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
- Software Testing
- Clinical Testing

A. Performance Testing

The Rika Plasma Donation System utilizing the Individualized Nomogram 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. Software Testing

Software testing was successfully conducted, and documentation was provided in alignment with Enhanced Documentation requirements of FDA's Guidance for Industry and FDA Staff, "Contents of Premarket Submissions for Device Software Functions."

C. Clinical Studies

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 nomogram for plasma donations. The study collected 124 evaluable plasma products at 2 investigative sites in the US.

Primary endpoint

The primary endpoint of the investigation was the proportion of plasma products with an acceptable plasma collection volume as determined by the individualized nomogram. The overall procedure success was achieved in 100% of the procedures in the Evaluable Analysis Set. The lower bound of a one-sided 95% confidence interval was 0.9761 which is above 0.95, demonstrating that the test product met the individualized nomogram.

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 serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) reported during this study.

VII. CONCLUSIONS

Based on the results of the non-clinical and clinical tests performed on the Rika Plasma Donation System utilizing the individualized nomogram, 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.