510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary is provided.

510(k) Summary

I. SUBMITTER

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Date Prepared: DATE

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.

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 with modified saline hook to the predicate device.

Category	Subject Device	Predicate Device	Comparison
Device Name	**Rika Plasma Donation System**	**Terumo BCT: Rika Plasma Donation System**	N/A
Classification Name	Automated blood cell separator	Automated blood cell separator	Same
Regulatory Number	21 CFR Part 864.9245	21 CFR Part 864.9245	Same
Product Code	GKT	GKT	Same
Class	II	II	Same
Indication for Use	Collection of Source Plasma	Collection of Source Plasma	Similar
Fundamental Scientific Technology	Channel based centrifugal separation	Channel based centrifugal separation	Similar
Software	Embedded + Protocol	Embedded + Protocol	Same
Saline Hook	Modified Wide Hook	Wide Hook	Similar

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

A. Performance Testing

The Rika Plasma Donation System with the modified saline hook was tested against its performance requirements through demonstration and direct testing. The testing showed that the Rika Plasma Donation System performed according to its performance requirements and is usable by the intended users.

VII. CONCLUSIONS

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