5 510(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

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

Contact Person: Brittany Grochala
Title: Specialist, Regulatory Affairs
Phone: 303-205-2612
Fax: 303-231-4756

Date Prepared: 03/21/2019

II. DEVICE

Trade Name of Device: Trima Accel® Automated Blood Collection 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 Class: In accordance with 21 CFR 864.9245(b), the classification for this device is Class II with special controls.
Product Code: GKT

III. PREDICATE DEVICE

Table 1: Predicate and Reference Device Information

Device	Product Classification	Trade Name Of Predicate Device	Manufacturer and 510(k) Holder	510(k) Clearance Number
Predicate	Class II	Trima Accel® Automated Blood Collection System	Terumo BCT	BK170157

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

A. Device Identification

Trima Accel® Automated Blood Collection System Version 7

B. Device Characteristics

The Trima Accel system is an automated blood component collection system that uses centrifugal force to separate whole blood into platelet, plasma, and red blood cell components. These blood

components are either collected into storage bags or returned to the donor depending on the procedure selected at the time of collection. The Trima Accel system consists of three subsystems:

1. The Trima Accel system
2. Embedded software
3. Single use, Disposable Tubing Sets

The products collected depend on the disposable tubing collection set used, the donor-specific parameters (donor's total blood volume, hematocrit, and platelet count) entered at the time of collection, and the procedure selected. Donor blood type may also be used to limit which blood components are collected. Depending on the disposable tubing set used, the Trima Accel system may collect the following products alone or in combination, depending on the approval of the disposable tubing set:

- Platelets pheresis (single, double, or triple units)
- Platelets pheresis, Leukocytes Reduced (single, double, or triple units)
- Plasma
- Plasma, Leukocytes Reduced
- AS-3 Red Blood Cells (single or double units)
- AS-3 Red Blood Cells, Leukocytes Reduced (single or double units) utilizing an integrated filter

C. Device Description

The Trima Accel® Automated Blood Collection System is an automated blood component collection system that uses centrifugal force to separate blood into platelet, plasma, and red blood cell components. These components are either collected into storage bags or returned to the donor depending on the blood components needed by the blood center.

D. Environment of Use

The operation of the Trima Accel system is performed by professionally-trained apheresis operators in a blood center, on mobile blood drives, or hospital laboratory environment. 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 phlebotomists, nurses, and laboratory technicians.

E. Key Performance Specifications/Characteristics of the Device

The Trima Accel system is an automated blood component collection system that uses centrifugal force to separate whole blood into platelet, plasma, and red blood cell components
These blood components are either collected into storage bags or returned to the donor depending on the procedure selected at the time of collection. The peristaltic pumps draw blood into the system and move components into the product bags or return them to the donor.

V. INTENDED USE

The Trima Accel system is an automated blood cell separator intended for use in collecting blood components for later transfusion into patients. The intended use has not changed from that of the predicate device.

VI. INDICATIONS FOR USE

The Indications for Use statement for the Trima Accel system is not identical to predicate device. InterSol platelet additive solution has been added as an optional storage solution for platelets. This difference does not alter the intended use of the device nor does it affect the safety and effectiveness of the device relative to the predicate. Both the subject and the predicate device have the same intended use.

VII. TECHNOLOGICAL COMPARISON

There are no technological differences between the subject and predicate device.

VIII. PERFORMANCE DATA

The following performance data is provided in support of the substantial equivalence determination.

Table 2: Performance Data

Type	Method
Clinical	The Trima Accel system was used in two clinical trials: • Study 1 conducted under IDE 16145 validated the In Vitro quality of platelets collected on Trima Accel and stored in InterSol Solution for 1, 5, and 7 days • Study 2 conducted under IDE 16145 validated the In Vivo quality of platelets collected on Trima Accel and stored in InterSol Solution for 5 days

A. Clinical Studies

Clinical testing of the Trima Accel® device included two clinical studies that had a combined total of 120 healthy donors. Substantial equivalence was based in part on the clinical study.

In Vitro Platelets in InterSol Study

This was a randomized, paired, prospective, open-label, multicenter, controlled study to evaluate the safety and performance of using the Fresenius Kabi's InterSol solution (platelet additive solution) as a partial substitute for plasma when added immediately to platelets collected on the Trima Accel system compared to platelets collected and stored in 100% plasma. Eighty-seven (87) healthy donors were enrolled to obtain 60 paired donations which were included in the Full Analysis Set (FAS).

Effectiveness Endpoints

The primary endpoints for this study were the pH at Day 5 and Day 7.

1. pH of platelets ≥ 6.2 collected on the Trima Accel system and stored in InterSol for 5 days.

2. pH of platelets ≥ 6.2 collected on the Trima Accel system and stored in InterSol for 7 days.

Primary safety endpoint
Safety was monitored through collection of adverse events (AEs), serious adverse events (SAEs), and unanticipated adverse device effects (UADEs).

Effectiveness
All Test products met the FDA acceptance criteria for pH of platelets stored in InterSol platelet additive solution for 5 and 7 days.

The primary endpoint for the In Vitro study focused on the pH ≥ 6.2 of platelets collected via the Trima Accel system and stored in InterSol for 5 and 7 days.

All Test products had a pH ≥ 6.2 at Day 5 and Day 7. Analysis of all paired collections showed all collections were successful. The one-sided 95% confidence interval was 0.951 indicating all products met the FDA acceptance criteria.

Secondary endpoint analysis of partial pressure of oxygen (pO2), partial pressure of carbon dioxide (pCO2), bicarbonate (HCO3-) lactate, glucose, lactate dehydrogenase (LDH), extent of shape change (ESC), hypotonic shock response (HSR), morphology, and P-selectin was performed on Day 5 and Day 7. Morphology met the established acceptance criteria but ESC, HSR, and P-selectin values did not; however, the ESC, HSR, and P-selectin values were comparable to what has been reported previously for platelets stored in InterSol Solution.

Safety
The study reported 87 patients with a total of 0 serious adverse events (SAEs).

Patient Accountability

Disposition	Overall
Number of Participants	87
Screen Failure	2
Safety Population	85
Full Analysis Set Population	60
Excluded from Full Analysis Set Population	25
Inability to collect 2 complete paired platelet and 1 concurrent plasma unit(s)	14
Incomplete or incorrect post-collection processing due to equipment failure or malfunction	1
Any collected product falls outside of the Trima Accel platelet product storage boundaries	11
>$5.1x10^{11}$ total platelets	5
Platelet product concentrations outside of 0.7 to 2.1 x 10^6/µL	6

In Vivo Platelets in InterSol Study

This was a prospective, open-label, multicenter, controlled study to evaluate the in vivo recovery and survival of radiolabeled apheresis platelets collected on the Trima Accel system and stored in 65% InterSol / 35% plasma for 5 days. Thirty-three (33) participants were enrolled in the study to collect 24 evaluable recovery and survival data points.

Effectiveness Endpoints
The primary endpoints for this study were the recovery and survival of platelets as calculated using the COST software.

1. For recovery: Test – (0.66 × Control) ≥ 0 with a 1-sided 97.5% confidence limit
2. For survival: (Test/24) – (0.58 × [Control/24]) ≥ 0 with a 1-sided 97.5% confidence limit

Primary safety endpoint
Safety was monitored through the collection of adverse events (AEs), serious adverse events (SAEs), and unanticipated adverse device effects (UADEs) from the start of the apheresis procedure until study completion.

Effectiveness
Platelet recovery and survival for platelets collected on the Trima Accel system and stored in InterSol platelet additive solution for 5 days met FDA acceptance criteria. Mean platelet recovery and survival were 45% and 5.4 days, respectively, for the test platelets.

The primary endpoint for the In Vivo study focused on the recovery and survival of radiolabeled apheresis platelets collected on the Trima Accel system and stored in 65% InterSol / 35% plasma for 5 days

The average recovery of Test platelets was 45.2% ± 12.26% and the average recovery of the Fresh Control platelets was 56.0% ± 13.16%. This resulted in a Test – (0.66 × Control) mean difference of 8.18 ± 9.835% and a lower limit of a 1-sided 97.5% confidence interval of 4.03%. The average survival of the Test platelets was 5.4 ± 0.99 days and the average survival of the Fresh Control platelets was 7.9 ± 1.48 days. This resulted in a (Test/24) – (0.58 × [Control/24]) mean difference of 0.80 ± 0.967 days and a lower limit of a 1-sided 97.5% confidence interval of 0.39 days. As the lower limit of the 97.5% confidence interval for both platelet recovery and survival was > 0, platelets collected on the Trima Accel system and stored in 65% InterSol / 35% plasma for 5 days met the FDA acceptance criteria for platelet recovery and survival.

Safety
The study reported 33 patients with a total of 0 serious adverse events (SAEs).

Patient Accountability

Disposition	**Site 1 (n=19)**	**Site 2 (n=14)**	**Total (N=33)**
Enrolled	19	14	33
Screen Failure	1	0	1
Participants who completed the study, n (%)	14 (73.7)	12 (85.7)	26 (78.8)
Participants who discontinued the study, n (%)	4 (21.1)	2 (14.3)	6 (18.2)
Development of an AE that interfered with the participant's continued participation, n (%)	1 (5.3)	0 (0.0)	1 (3.0)
Inability to collect a complete platelet unit, n (%)	0 (0.0)	1 (7.1)	1 (3.0)
Trima flag that results in the test product having and insufficient yield, leukoreduction, or additive solution, n (%)	1 (5.3)	0 (0.0)	1 (3.0)
Product damaged during storage, n (%)	2 (10.5)	0 (0.0)	2 (6.1)
Positive bacterial test, n (%)	0 (0.0)	1 (7.1)	1 (3.0)

Summary

Based on the clinical performance as documented in the clinical studies, InterSol Solution is an effective PAS for platelets collected on the Trima Accel System and stored for 5 or 7 days.

IX. CONCLUSIONS

Based upon the clinical tests performed on the subject device, the Trima Accel system is shown to be as safe and effective as the legally marketed predicate device. Additionally, the information provided in this 510(k) demonstrates that InterSol is an effective PAS solution for platelets collected on Trima Accel.