

**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**

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**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	GKT	Trima Accel® Automated Blood Collection System	Terumo BCT, Inc.	BK120049
Reference	GKT	Trima Accel® Automated Blood Collection System	Terumo BCT, Inc.	BK140158

**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

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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 intended use of Trima Accel 7 is identical to that of the predicate and reference devices.

## **VI. INDICATIONS FOR USE**

The Indications for Use statement for the Trima Accel 7 is not identical to predicate device. The testing stipulation for hyperconcentrated triple products has been removed. 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.

**VII. TECHNOLOGICAL COMPARISON**

A comparison between the predicate and/or reference device to the subject device is provided in the following table.

**Table 2: Attribute Comparison**

<b>Attribute/Feature</b>	<b>Comparison to Predicate and/or Reference Device</b>
<b>Intended Use</b>	The Intended use for the Trima Accel 7 is identical to that of the predicate and reference devices.
<b>Essential Technology</b>	The predicate, reference, and subject Trima Accel systems are automated blood component separators. They achieve their essential function of blood separation through centrifugation. The change in software does not impact the essential technology.
<b>Hardware or “Equipment”</b>	The predicate, reference, and subject Trima Accel systems have the same hardware/equipment. The change in software does not impact the hardware/equipment.
<b>Disposable Tubing Set</b>	The change in software did not impact the disposable tubing sets. The predicate, reference, and subject Trima Accel systems use the same disposable tubing sets.
<b>Software</b>	The software is different between the subject device and the predicate/reference device. This is the subject of the 510(k) notification. The differences include improvements to platelet leukoreduction, platelet yield, and procedure time. These changes do not impact the safety or effectiveness of the device.

**VIII. PERFORMANCE DATA**

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

<b>Type</b>	<b>Method</b>
Software	The Trima Accel system software development and verification followed a life-cycle approach. The software testing and verification activities included design reviews, hazard analysis, code reviews and software testing. Software tests included safety tests, functional tests and reliability tests. Testing also included normal, as well as limit and failure conditions.
Specification Testing	System requirements were reviewed for impact by the modification to the software. Verification testing was conducted on impacted Lower Level system requirements and validation testing was conducted on impacted Product Requirements.
Clinical Testing	The Trima Accel system software was used in a clinical trial conducted under IDE which validated the leukoreduction performance of the Trima Accel V7 software.

**A. Software Verification Testing**

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

## **B. Clinical Studies**

Clinical testing of the Trima Accel 7 included two clinical studies that had a combined total of 699 healthy donors. Substantial equivalence was based in part on the clinical studies.

### **Platelets in Plasma Clinical Study**

The platelets in plasma study was a prospective, open-label, multicenter, controlled study to evaluate the leukoreduction of platelets stored in 100% plasma collected on the Trima Accel Automated Blood Collection System Version 7 software enhancements. Three hundred and thirty-four (334) healthy donors were enrolled, and 279 products were included in the evaluable data set.

#### ***Location of Study***

The study was conducted under IDE 16676 at locations within the United States only.

#### ***Effectiveness Endpoints***

The primary endpoints for this study were the proportion of platelet products with an acceptable residual WBC level. The acceptable residual WBC counts were:

- Single = residual WBC level  $< 5.0 \times 10^6$
- Double = residual WBC level  $< 8.0 \times 10^6$  or  $< 5.0 \times 10^6$  for each transfusable unit
- Triple = residual WBC level  $< 12.0 \times 10^6$  or  $< 5.0 \times 10^6$  for each transfusable unit

The secondary endpoints for this study were the proportion of platelet products with an acceptable platelet yield. The acceptable platelet yield for single, double, and triple platelet products were:

- Single platelet yield  $\geq 3.0 \times 10^{11}$
- Double platelet yield  $\geq 6.2 \times 10^{11}$
- Triple platelet yield  $\geq 9.3 \times 10^{11}$

#### ***Safety Endpoint***

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

#### ***Effectiveness***

The primary endpoints for the platelets in plasma study focused on the leukoreduction of single, double, and triple platelet products.

It was determined with 95% confidence that 95% of the single, double, and triple platelet products had acceptable residual WBC levels. Primary endpoint analysis showed only 1 platelet product had a residual WBC count above the acceptable level out of 279 evaluable platelet products collected. The 1 failure occurred during the collection of a single platelet product and there were no failures in the double or triple platelet products.

It was determined with 95% confidence that at least 75% of the single, double, and triple platelet products had an acceptable platelet yield. Secondary endpoint analysis showed only 1 platelet unit had a platelet yield below the acceptable limit out of 279 evaluable platelet products

collected. This platelet unit was a single platelet product and there were no failures in the double or triple platelet products.

**Safety**

The study reported 334 participants with a total of 0 serious adverse events (SAEs).

**Participant Accountability**

<i>Stage</i>	<i>Single</i>	<i>Double</i>	<i>Triple</i>	<i>Unassigned</i>	<i>Total</i>
<i>Enrollment</i>	97	95	95	47	334
<i>Screen Failure, n</i>	0	0	0	19	19
<i>Did not start apheresis procedure, n</i>	0	0	0	5	5
<i>Participants who Completed Study, n(%)</i>	94 (96.9)	95 (100)	95 (100)	1 (4.3)	285 (91.9)
<i>Participants who Discontinued Study, n(%)</i>	3 (3.1)	0	0	22 (95.7)	25 (8.1)
<i>Development of an AE that interfered with the participant's continued participation, n(%)</i>	0	0	0	13 (56.5)	13 (4.2)
<i>Subject refused further treatment and/or follow-up and withdrew consent, n(%)</i>	2 (2.1)	0	0	0	2 (0.6)
<i>Investigator decision, n(%)</i>	0	0	0	1 (4.3)	1 (0.3)
<i>Other, n(%)</i>	1 (1.0)	0	0	8 (34.8)	9 (2.9)

Abbreviations: AE= adverse event; n=number

**Platelets in PAS Clinical Study**

The platelets in Platelet Additive Solution (PAS) study was a prospective, open-label, multicenter, controlled study to evaluate the leukoreduction of platelets stored in PAS collected on the Trima Accel Automated Blood Collection System Version 7 software enhancements. Three hundred sixty-five (365) healthy donors were enrolled and 279 products were included in the evaluable data set.

**Location of Study**

The study was conducted under IDE 16676 at locations within the United States only.

**Effectiveness Endpoints**

The primary endpoints for this study were the proportion of platelet products with an acceptable residual WBC level. The acceptable residual WBC counts were:

- Single = residual WBC level <  $5.0 \times 10^6$
- Double = residual WBC level <  $8.0 \times 10^6$  or <  $5.0 \times 10^6$  for each transfusable unit
- Triple = residual WBC level <  $12.0 \times 10^6$  or <  $5.0 \times 10^6$  for each transfusable unit

The secondary endpoints for this study was the proportion of platelet products with an acceptable platelet yield. The acceptable platelet yield for single, double, and triple platelet products were:

- Single platelet yield  $\geq 3.0 \times 10^{11}$
- Double platelet yield  $\geq 6.2 \times 10^{11}$
- Triple platelet yield  $\geq 9.3 \times 10^{11}$

***Safety Endpoint***

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

***Effectiveness***

The primary endpoint for the platelet in PAS study focused on leukoreduction of single, double, and triple platelet products.

It was determined with 95% confidence that 95% of the single, double, and triple platelet products had acceptable residual WBC levels. The primary endpoint analysis showed none (0) of the platelet products collected in this study had a residual WBC count above the acceptable level.

It was determined with 95% confidence that at least 75% of the single, double, and triple platelet products had an acceptable platelet yield. For the secondary endpoint, 4 platelet units had a platelet yield below the acceptable limit out of 279 evaluable platelet products collected. All 4 platelet units were a single platelet product. There were no failures in the double or triple platelet products.

***Safety***

The study reported 365 participants with a total of 0 serious adverse events (SAEs).

***Participant Accountability***

<i>Stage</i>	<i>Single</i>	<i>Double</i>	<i>Triple</i>	<i>Unassigned</i>	<i>Total</i>
<i>Enrollment</i>	99	101	100	65	365
<i>Screen Failure, n</i>	0	0	0	25	25
<i>Did not start apheresis procedure, n</i>	0	0	0	5	5
<i>Participants who Completed Study, n(%)</i>	96 (97.0)	100 (99.0)	100 (100.0)	7 (20.0)	303 (90.4)
<i>Participants who Discontinued Study, n(%)</i>	3 (3.0)	1 (1.0)	0 (0.0)	28 (80.0)	32 (9.6)
<i>Development of an AE that interfered with the participant’s continued participation, n(%)</i>	3 (3.0)	1 (1.0)	0 (0.0)	10 (28.6)	14 (4.2)
<i>Participant refused further treatment and/or follow-up and withdrew consent, n(%)</i>	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	1 (0.3)
<i>Other, n(%)</i>	0 (0.0)	0 (0.0)	0 (0.0)	17 (48.6)	17 (5.1)

Abbreviations: AE= adverse event; n=number

***Summary of Clinical Studies***

Based on the clinical performance as documented in the two clinical studies, the Trima Accel Automated Blood Collection System Version 7 software enhancement was found to have a safety and effectiveness profile that is similar to the predicate device.

**IX. CONCLUSIONS**

Based on the non-clinical and clinical tests performed on the proposed Trima Accel 7, it is as safe and effective as the legally marketed predicate device. The information provided in the 510(k) demonstrates that the Trima Accel 7 is substantially equivalent to the identified predicate device.