

510(k) Summary

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Trade Name of Device: Trima Accel® System

Common Name: Automated Blood Component Collection System

Classification Name: Automated Blood Cell Separator
In accordance with 21 CFR 864.9245(b), the classification for this device is Class II with special controls.

Predicate Devices: BK120017 Trima Accel Automated Blood Component Collection System Version 6.0.3
BK110068 Trima Accel Automated Blood Component Collection System Version 5.1.9

Device Description:

The Trima Accel® System is an automated blood component collection system that uses centrifugal force to separate blood into platelet, plasma, red blood cell components and uses ACD-A as an anticoagulant.

This Notification adds the ability to collect Apheresis Plasma Frozen Within 24 Hours (PF24RT24) which can be used as replacement for non-labile clotting factors. This product is not equivalent to FFP. There are no manufacturing, software, hardware or disposable tubing set changes to the Trima Accel system.

Indications for Use:

The Trima Accel system is an automated blood cell separator intended for use in collecting blood components for later transfusion into patients.

Depending on the disposable tubing set used, the Trima Accel system has been cleared to collect:

- Double ACD-A/AS-3 Red Blood Cells (leukocytes reduced or not leukoreduced)
- Or the following products, alone or in combination:
- ACD-A/AS-3 Red Blood Cells
 - ACD-A/AS-3 Red Blood Cells, Leukocytes Reduced utilizing an integrated filter (TLR gravity drain filter or AutoRBC filter)
 - Platelets Pheresis, Leukocytes Reduced (single, double, or triple units)
 - Plasma
 - Fresh Frozen Plasma and Fresh Frozen Plasma, Leukocytes Reduced
 - Must be prepared and placed in a freezer at -18° C or colder within 8 hours of collection.
 - Source Plasma

- Plasma Frozen Within 24 Hours After Phlebotomy (PF24) and Plasma Frozen Within 24 Hours After Phlebotomy, Leukocytes Reduced
 - Must be stored at 1-6°C within 8 hours of collection and prepared and frozen within 24 hours after phlebotomy.
 - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.

- Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy (PF24RT24) and Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy, Leukocytes Reduced
 - Can be stored at room temperature for up to 24 hours after collection. Product must be prepared and frozen within 24 hours after phlebotomy.
 - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.

Platelets Pheresis (single, double, or triple units) may be manufactured from products that do not meet leukocyte reduction product standards.

The Trima Blood Component Sampling Assembly, which is either integrated into the disposable tubing sets or as an accessory for sterile connection, is intended to allow aseptic removal of a sample from the platelet bag for subsequent bacterial or other applicable testing. The Sampling Assembly does not have contact with blood fluids that are reinfused to a donor or patient.

- Adequate studies have not been performed to evaluate the effect of gamma irradiation or freezing on the quality of ACD-A/AS-3 red blood cells products (RBCs) collected with gravity drain leukoreduction process (TLR filter) on the Trima Accel system.
- Studies have not been performed to support gamma irradiation or freezing of ACD-A/AS-3 RBCs collected with an integrated in-line RBC leukoreduction filter(s) (AutoRBC filter) on the Trima Accel system.

RBCs collected on the Trima Accel system using the AutoRBC feature as either a single unit or double units, with continuous RBC leukoreduction, and stored in ACD-A/AS-3 for 42 days met the following acceptance criteria required by the FDA-CBER:

Primary Outcomes

- 95% probability and a one-sided 95% confidence limit:
 - the number of contaminating leukocytes per unit is less than 5 million
 - the recovery of RBCs after leukoreduction is greater than 85%
 - RBC hemolysis is less than 1.0%
- The mean recovery at 24 hours for each unit is $\geq 75\%$ with standard deviation $\leq 9\%$; and the one sided 95% lower confidence limit for the population proportion of successes is $>70\%$ (successes = individual units recovery $\geq 75\%$).

Secondary Outcomes

The results of biochemical tests for ATP and Potassium levels at the end of storage failed to show with 95% confidence that greater than 95% of the products will be within 20% of the Control product. Results of ATP levels for Test for a single RBC collection were not significantly different from Control by a paired t test analysis (p-value = 0.80). Results of ATP levels for Test for double RBC collections were

significantly better than Control by a paired t test analysis (two-sided p-value = 0.014). Results of Potassium levels for Test for a single RBC collection were significantly better than Control by a paired t test analysis (p-value = 0.0354). Results of Potassium levels for Test for double RBC collections were not significantly different from Control by a paired t test analysis (two-sided p-value = 0.566).

The pH results support the conclusion with 95% confidence that more than 95% of the products will have a difference between Test and Control of less than 0.5 pH units at the end of RBC shelf life. The clinical significance of the secondary outcomes is unknown.

The Trima Accel system includes a modified platelet post-count algorithm. U.S. customers should not set the minimum post-count below 100,000/ μ L. This clearance applies only to plasma-stored platelets.

The Auto PAS feature has not been cleared for use in the United States. This feature is disabled in the software.

The table below summarizes the plasma product parameters from a paired study comparing PF24RT24 (apheresis plasma held at room temperature and frozen 24 hours post-collection) and FFP (apheresis plasma held at room temperature and frozen 8 hours post-collection).

Summary of PF24RT24 (Test) and FFP (Control) Plasma Product Parameters (N=52)							
Coagulation Assay	Mean (SD)		Median		(Minimum, Maximum)		Mean Difference (Test- Control) (95% Confidence Interval)
	Control	Test	Control	Test	Control	Test	
PT (seconds)	12.0 (0.6)	12.1 (0.6)	11.8	12.0	10.7, 13.7	10.9, 13.8	0.1 (0.1, 0.2)
aPTT (seconds)	37.9 (3.9)	38.5 (3.8)	37.7	38.5	31.1, 47.7	31.6, 48.6	0.6 (0.2, 0.9)
Factor V (IU/dL)	100.4 (17.6)	99.5 (16.5)	102.5	100.5	52, 138	52, 136	-0.9 (-2.0, 0.2)
Factor VIII (IU/dL)	79.8 (25.0)	72.6 (24.1)	74.0	67.5	37, 163	36, 157	-7.2 (-9.3, -5.1)
Factor XI (IU/dL)	73.5 (11.4)	73.8 (11.0)	71.5	71	53, 109	52, 103	0.3 (-0.4, 1.0)
vWF (IU/dL)	91.7 (29.1)	89.4 (28.2)	90.5	87	44, 145	41, 145	-2.3 (-4.2, -0.4)
Protein C (IU/dL)	97.9 (14.0)	94.3 (13.4)	99	98	65, 123	62, 126	-3.7 (-5.5, -1.9)
Protein S (IU/dL)	93.3 (20.0)	83.0 (19.2)	91.5	80.5	53, 161	48, 145	-10.3 (-12.4, -8.2)
AT III (IU/dL)	103.1 (7.7)	102.8 (7.8)	103	102.5	85, 120	85, 116	-0.3 (-1.4, 0.9)
Factor VIIa	2.6 (1.2)	2.7 (1.3)	2.4	2.3	0.6, 6.1	1.2, 6.4	0.1 (-0.3, 0.4)
FPA	9.2 (12.2)	9.9 (11.1)	4.0	4.9	0.6, 57.5	0.4, 44.9	0.6 (-3.4, 4.7)

Technological Comparison:

There are no changes to the Trima Accel system other than the Indications for Use statement. The software, hardware and disposable tubing sets are identical to the predicate systems.

Substantial Equivalence:

Provided below is a summary of substantial equivalence.

Table 1: Key Similarities - Trima Accel System vs. Predicate

Attribute		Comparison
1	Intended Use / Labeling	The Intended use has been revised to include a claim for PF24RT24. All other labeling is the same when compared to the predicate.
2	Essential Technology	Both Trima Accel systems are automated blood component separators. They achieve their essential function (the separation of blood cells and plasma) through centrifugation.
3	Materials	N/A – there are no material changes provided in this Notification.
4	Sterility / Manufacturing	N/A – there are no manufacturing changes provided in this Notification.
5	Clinical Performance	The results of the study demonstrate that, for the series of plasma quality assays evaluated, that plasma collected on Trima Accel system then frozen within 24 hours can be used as a suitable replacement for non-labile clotting factors.