Trima Accel Automated Blood Component System

Summary of Safety and Effectiveness
BK010046 and BK010050

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Trade Name of Device:	Trima Accel Automated Blood Component Collection System.
Common Name:	Automated Blood Component Collection System
Classification Name:	Automated Blood Cell Separator (21 CFR 864.9245)
Predicate Devices:	Trima Automated Blood Component Collection System (510(k)'s BK970002, BK970023, BK990025, BK010006)

Device Description

The Trima system is an apheresis device intended for use in the collection of leukoreduced blood components from donors. It has the potential to collect the following combinations of components. There are no new component combinations resulting from implementation of the single stage separation technology on the Trima Accel System.

- Single Donor Platelets (SDP)
- Double Platelet Products (DPP)
- Triple Platelet Products (TPP)
- SDP or DPP or TPP and a Unit(s) of Plasma
- SDP or DPP or TPP and a single unit Red Blood Cell (RBC) Product in AS-3
- SDP, a Unit of Plasma, and a single unit RBC Product in AS-3
- Single Unit RBC Product (SRBC) in AS-3
- Double Unit RBC Products (DRBC) in AS-3
- Single Unit RBC in AS-3 and Unit(s) of Plasma
- Unit(s) of Plasma

FDA in 510(k)'s BK970005, BK970023, and BK990025 originally cleared the collection of these product combinations. These submissions address the

collection and storage of platelet, plasma and red blood cell products using the Trima Accel System.

Intended Use:

This device is intended for the collection, pre-storage leukoreduction, and storage of platelet, plasma and RBC units. The blood products collected depend on the needs of the blood center and the weight, total blood volume and hematocrit of the donor. The new disposable channel configuration and filler, in combination with the new software upgrade will enhance the platelet collection efficiency of the Trima system.

Technological Comparison:

The Trima Accel disposable tubing set is equivalent to the sets used with the original Trima System. It generally uses the same materials, including the platelet and plasma storage bags. The packaging and sterilization process are the same, and both sets are manufactured in comparable GMP-controlled medical manufacturing areas in the same plant.

The Trima Accel equipment uses the same centrifugal separation concept as the original Trima System except for the single stage versus dual stage separation technology. The Trima Accel equipment is approximately 42 inches tall and 21 inches wide, and weighs less than 200 pounds, making it easy to transport. This automated system separates whole blood into its major components: platelets, plasma, and red blood cells. The Trima Accel System uses a disposable tubing set with a cassette that automatically loads the tubing into the pumps, valves, and sensors. The touch screen display is designed to lead the Operator through the setup and operating procedures, and provide her/him with detailed alarm messages to assist in troubleshooting procedures.

The equipment uses five peristaltic pumps located on the front panel. Blood is drawn from the donor and into the system by the inlet pump during the collection process. AC and whole blood are mixed at the configured inlet to AC ratio as a result of the inlet and AC pump speeds. The blood and AC mixture then enters the single stage separation channel in the centrifuge. As the whole blood is separated, the collect and plasma pumps remove platelets and plasma. RBCs are pushed from the channel into the collect bag or reservoir by the pressure created from the inlet pump forcing more blood into the channel. Components not collected are directed to a reservoir on the cassette.

When the reservoir contains a sufficient volume of uncollected RBCs, plasma and platelets, a sensor is triggered which activates the return pump. The return pump interrupts the flow of incoming blood by pumping the return blood back through the single needle access to the donor until the level in the reservoir reaches the lower level sensor. During platelet and plasma collection the inlet pump remains at a constant speed, forcing a small amount of blood back through

the inlet line and into the channel. This recirculated blood allows the Trima Accel System to maintain a continuous flow of blood through the channel, which stabilizes the separation process. During RBC collection, blood is not recirculated to avoid diluting the incoming donor blood.

A saline replacement fluid option is available on the Trima Accel System for the DRBC, RBC plus Plasma, and Plasma Only protocols. It is not available when platelet products are collected. This automated option can be activated at the discretion of the blood center's Medical Director or medical staff.

Discussion of Clinical Data:

The safety and efficacy of the Trima Accel System were validated to collect platelet, plasma and red blood cell products in a series of studies.

Platelet Product Quality

Back to back platelet collection procedures were done. Each study center completed ten (10) paired runs, each collecting a single platelet product from the Trima Accel system and a single platelet product using the current Trima System (Version 4). The order of collection was randomized such that half of the procedures had a Trima Accel platelet product collected first, and half had a Trima Version 4 platelet product collected first.

In vitro platelet assays were used to evaluate the platelet products collected using the Trima Accel System. The platelet products were sampled on Day 0, and a series of *in vitro* platelet function assays were performed. The platelet products were stored for 5 days, and the *in vitro* platelet assays were repeated. There were no statistically significant differences in the results for the major parameters including platelet yield, platelet concentration, WBC contamination levels, platelet morphology, hypotonic shock response, or p-selectin (GMP-140) expression. There were statistically significant differences in some instances, but these values were not clinically significant. Platelet products collected using the Trima Accel Stage system met both the current and proposed leukoreduction standards as described by FDA-CBER in its leukoreduction guidelines. These data demonstrate the clinical efficacy of the platelets collected using the Trima Accel System, and predict that the collected platelet products will be effective when transfused.

Plasma Product Quality

The results from plasma component assays demonstrate that the Trima Accel System can collect concurrent plasma during platelet and red cell collection procedures, or with plasma units collected alone. The studies comparing the plasma products collected on the Trima Accel System to those collected on original Trima System showed that the plasma products were comparable, with no clinically significant differences. The mean levels of Factor VIII were well

above the 50 International Units per product required by the AABB standards. These plasma units were also leukoreduced, meeting both U.S. F.D.A. and European standards for leukoreduced blood components.

Packed Red Blood Cell Unit Quality

Packed red cell units were collected as single or double units using the Trima Accel System and stored with AS-3 for 42 days at 4 °C. Samples were collected from pRBC units and analyzed with *in vitro* red cell function assays. These results showed less than 1% hemolysis, with appropriate retention of the ATP concentration known to correlate with red cell recovery and survival. Individual red cell units collected during a double red cell collection were shown to be equivalent to each other. These RBC units were also shown to be equivalent to units collected with a concurrent plasma unit, and units collected following a platelet collection procedure. The red cell unit's leukoreduced with the integrated TLR filter met both U.S. F.D.A. and European standards for leukoreduced blood components.

Conclusion

The data collected during the Trima Accel clinical studies evaluating the collection and storage of platelet, plasma and RBC products predict that these products will be safe and effective when transfused. The results from the products collected during these procedures showed no clinically significant differences when compared to products collected using the original Trima System.

These data demonstrate that the Trima Accel System can safely and effectively collect combinations of leukoreduced platelet, plasma, and RBC products. These products are equivalent to those processed from whole blood, and the automated collection process can replace the need to collect whole blood units.

Manufacturers Recommendations

Fresh Frozen Plasma Freezing Recommendation

Fresh Frozen Plasma collected using the Trima System should be frozen within 8 hours of the time of the venipuncture since the plasma is collected as a 'by-product' of the platelet procedure.

Collection of DRBC Products from Small Donors

Gambro BCT recommends that donors should have at total blood volume larger than 4.5 liters to donate Double Red Blood Cell units. Controlled clinical studies have not been done with donors who have total blood volume less than this recommendation.

Leukoreduction of pRBC Units

Gambro BCT recommends that Trima Accel RBC unit's leukoreduced with the integrated TLR filter be filtered at room temperature within 8 hours of collection.

Freezing Red Blood Cell Units

Studies have not been done to support freezing of ACDA/AS-3 RBC products.

Irradiating Red Blood Cell Units

Studies have not been done to support irradiation of ACDA/AS-3 RBC products.