6 510(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

Trade Name of Predicate Device: Trima Accel® Automated Blood Collection System
Product Code: GKT
Manufacturer and 510(k) Holder: Terumo BCT, Inc.
510(k) Clearance Number: BK170157

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

A. Device Identification

Trima Accel® Automated Blood Collection System

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. 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.

D. 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.

E. Materials of Use

There were no new materials introduced to the Trima Accel system by the introduction of the new computers and software patch as compared to the predicate device.

F. 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/ INDICATIONS FOR USE

The is no change to the intended use/ indications for use for the Trima Accel system as a result of this modification.

VI. TECHNOLOGICAL COMPARISON

The modified Trima Accel system uses the same technological principles as the currently marketed device (BK170157). There is no change in separation technology used in the Trima Accel system and the collections process for platelet, plasma and red blood cell products is not impacted by the replacement of the obsolete CCAs that interface with the safety and control

computers and introduction of a software patch. There is no change in the manufacturing processes for the equipment or disposable tubing sets. The computer system design, software functionality, equipment, and tubing sets are identical. The only differences between the subject and predicate device are the new CCAs and driver updates to work with the computers' firmware. There are no changes to the system's fundamental scientific technology or principle of operation.

VII. PERFORMANCE DATA

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

A. Mechanical Testing

N/A. No changes were made to device physical specifications; no additional mechanical testing was required.

B. Biocompability Testing

N/A. No changes were made to device materials; no additional biocompatibility testing was required.

C. Electrical Safety and Electromagnetic Compatibility (EMC) Testing

Electrical safety and EMC testing were conducted on the *Trima Accel System*. The system meets all requirements of IEC 60601-1:2005 + A1:2012 (Edition 3.1), IEC 60601-1-6:2010 + A1:2013, IEC 60601-1-8: 2006 + A1:2012, and IEC 61010-1-2: 2014 (Edition 4) standards.

D. Software Verification and Validation Testing

Verification and validation testing of the *Trima Accel System* with the new computers and software patch met all the performance requirements, indicating that the subject device is as safe and performs as well as the predicate device.

E. Sterility Testing

N/A. This is not a sterile device.

F. Stability/Shelf Life Testing

N/A. No clinical studies were required to demonstrate substantial equivalent to the predicate device.

VIII. CONCLUSIONS

The modification of the new computers and software patch does not change the Trima Accel System's fundamental scientific technology or principle of operation; that is, the ability to use centrifugal force to separate whole blood into platelet, plasma, and red blood cell components. Additionally, the information provided in the 510(k) does not introduce new types of safety and effectiveness questions. In summary, the 510(k) demonstrates that the Trima Accel system with the new computers and software patch is substantially equivalent to the identified predicated device.