

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

Classification Name: Automated Blood Cell Separator (21 CFR 864.9245)
Regulatory Class: Class II with special controls.
Product Code: GKT

III. PREDICATE DEVICE

Trima Accel Automated Blood Collection System, BK150269, cleared August 6, 2015.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

A. Device Identification

The Trima Accel system is an automated blood component collection system that uses centrifugal force to separate whole blood into platelet, plasma, and/or 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:

- The Trima Accel system (Machine and Trima embedded software)
- Disposable Tubing Sets
- Optional Accessories, include:
 - o Accessory Storage Plasma Bag
 - o Accessory Storage Platelet Bag
 - o Trima Accel Seal Safe System

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.

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The Trima Accel system was first cleared on October 13, 1998, BK970023. This submission proposes changes to the peristaltic pumps to make them quieter.

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

The peristaltic pumps have been modified to make them quieter. This change does not affect the software, other mechanical components, or the disposable sets.

C. Environment of Use

The operation of the Trima Accel system is performed by professionally-trained apheresis operators in a blood center 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 nurses and laboratory technicians.

D. Device Description

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. The modifications to the pumps to make them quieter do not change the function of the pumps or the device.

E. Materials of Use

The only material that changed due to the introduction of quiet pumps was the hub bore. The hub bore that is a part of the current pump design is uncoated and the hub bore that is a part of the quiet pumps has an anodized Teflon coating.

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. The modifications to the pumps to make them quieter do not change the function of the pumps or the device.

V. INTENDED USE/ INDICATIONS FOR USE

There is no change to intended 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 (BK150269). The technological principle of the quiet peristaltic pumps on the subject device and the current peristaltic pumps on the predicate device are the same.

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 change to the pumps to make them quieter. There is no change in the manufacturing processes for the equipment or disposable tubing sets. The computer system design, electronics, equipment, and tubing sets are identical. The only difference between the subject and predicate device is a modification to the peristaltic pumps to make them quieter. 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 between the subject and predicate device. A summary of the verification testing and a summary of the validation testing was presented to show that the quiet pumps met all the performance requirements and that the subject device is as safe and performs as well as the predicate device.

VIII. CONCLUSIONS

Based on the verification and validation tests performed on the Trima Accel system with the quiet pumps, this system is as safe and effective as the legally marketed predicate device. The information provided in the 510(k) demonstrates that the Trima Accel system with the quiet pumps is substantially equivalent to the identified predicated device.