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510(K) SUMMARY

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Owner and Contact Person:

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Trade Name
ALYX Component Collection System

Common Name
Automated Blood Cell Separator (Centrifugal Separation Principle)

Classification Name
21 CFR 864.9245 Automated Blood Cell Separators

Automated blood cell separators which are based on centrifugation type technology have been classified by the Center for Biologics Evaluation and Research as **Class II** devices with Special Controls (Docket 2005N-0017, Final Rule, 30-Nov-07; updated March 2011 OMB Control No. 0910-0594).

Classification Panel
81 GKT (Hematology panel) - Separator, Automated, Apheresis

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed
Fresenius Kabi is claiming substantial equivalence with the currently marketed version of the ALYX Component Collection System cleared under 510(k) BK150236 on April 22, 2015.

Device Description
The ALYX Component Collection System is a continuous-flow, centrifugal device that separates whole blood into its components. The operator is responsible for preparing and monitoring the donor as well as operating and monitoring the ALYX instrument during the procedure.

The operator controls the instrument through a touch screen. When necessary, the operator is notified of potential problems with the procedure or instrument via messages on the screen with corresponding audible alarms.

Blood components are collected using sterile fluid path, single-use apheresis kits. These kits are provided in either closed or functionally closed configurations. The cells are centrifugally separated within the kit by density differences.

Modification to the Existing Device
Product labeling for the ALYX Component Collection System was updated to clarify the volume range for the device to process a single unit of red blood cells in a Single Unit Recovery (SUR) procedure. A service setting on the device will also be adjusted to reflect this volume range.

Indications for Use
The ALYX Component Collection System is intended for use in blood collection establishments to collect and separate whole blood into its components.

Depending on the ALYX Component Collection system apheresis kit used in the collection of products, the ALYX Component Collection system has been cleared for:

- Concurrent collection of two units of Red Blood Cells (2RBC), Leukocytes Reduced
  - Single Unit Recovery (One Unit of Red Blood Cells, Non-Leukocytes Reduced) permitted
- Concurrent collection of two units of Red Blood Cells (2RBC), Non-Leukocytes Reduced
  - Single Unit Recovery (One Unit of Red Blood Cells, Non-Leukocytes Reduced) permitted
- Concurrent collection of One Unit of Red Blood Cells, Leukocytes Reduced, and Plasma as
  - Fresh Frozen Plasma,
    - Must be prepared and placed in a freezer at -18°C or colder within 8 hours after phlebotomy.
  - Source Plasma
  - Plasma Frozen Within 24 Hours After Phlebotomy (PF24)
    - Must be stored at 1-6°C within 8 hours after phlebotomy and placed in a freezer at -18°C or colder 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)
    - *Can be stored at room temperature for up to 24 hours after phlebotomy. Product must be* placed in a freezer at -18°C or colder within 24 hours after phlebotomy
    - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
- Collection of Plasma as
  - Fresh Frozen Plasma,

        - Must be prepared and placed in a freezer at -18°C or colder within 8 hours after phlebotomy.
    - Source Plasma
    - Plasma Frozen Within 24 Hours After Phlebotomy (PF24)
        - Must be stored at 1-6°C within 8 hours after phlebotomy and placed in a freezer at -18°C or colder 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)
        - Can be stored at room temperature for up to 24 hours after phlebotomy. Product must be placed in a freezer at -18°C or colder within 24 hours after phlebotomy.
        - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.

Design Control Activities
The labeling change has no impact on the design of the ALYX Component Collection System. The modification described in this 510(k) does not add, delete, or modify the description of the ALYX Component Collection System. No changes were made to software, target collection volumes, separation method, disposable kit, or any other critical specifications.

Comparison of Technological Characteristics with the Predicate Device
Technological characteristics of the ALYX Component Collection System remain the same as the currently cleared device. The labeling change has no impact on the design of the device.

Performance Data
Performance data from previously cleared filings remain valid for demonstrating instrument and kit performance. A summary of a laboratory confirmation study is provided to demonstrate that the device still meets the performance claims with the proposed labeling change.

Conclusions
The ALYX Component Collection System with updated labeling described in this 510(k) is substantially equivalent to the currently marketed device.