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510(K) SUMMARY

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Device Trade Name
ALYX Component Collection System

Common Name/Usual 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).

Product Code and 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 ALYX Component Collection System most recently cleared for market under BK170001 on 04/03/2017. The modified ALYX closed kits have the same intended use as the closed kits originally cleared under BK010033 on 08/27/2002 and most recently cleared under BK170001 on 04/03/2017.

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
The currently marketed ALYX Component Collection System is being modified to include the following ALYX Apheresis Kits with an alternate Adsol solution container and an alternate ACD-A solution container subassembly with functionally equivalent materials to the previously cleared ALYX kits:

- X4R5700 ALYX RBC/Plasma Kit
- X4R5701 ALYX Red Kit
- X4R5720 ALYX 2RBC-LR Kit
- 4R5730 ALYX Plasma Kit

Statement of Intended Use/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.

No changes to the ALYX Component Collection System indications for use are requested in this Special 510(k) application.

Technological Characteristics as Compared to the Predicate Device

The technological characteristics of the ALYX Component Collection System and the ALYX apheresis kits remain the same as the predicate ALYX device. The proposed device and predicate device have the same performance characteristics and intended use. Modifications to add ALYX kits with alternate solution container subassemblies subject of this 510(k) does not add, delete, or modify the technological characteristics of the ALYX System or the disposable kits.

Performance Data

Performance testing and data in previously cleared ALYX filings remain valid for demonstrating instrument and disposable kit performance. Additional testing was performed to demonstrate that the ALYX kits with the alternate solution container subassembly meet existing specifications. The results of the testing were acceptable and demonstrate equivalence between the currently marketed device and the proposed device.

Conclusion

The fundamental scientific technology, intended use, safety and effectiveness of the ALYX Component Collection System remain unchanged. The verification testing performed in support of the ALYX kit with the alternate solution container subassembly described in this application provide a device system that is substantially equivalent to the currently marketed device.