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510(k) SUMMARY

Date Prepared

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Owner/Operator

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Device Trade Name

ALYX 2RBC-LR Kit

Common Name/Usual Name:

Automated Blood Cell Separator / Centrifugal Separation Principle

Other Marketing Names

ALYX Component Collection System ALYX ALYX System

Classification Name

21 CFR 864.9245 Automated Blood Cell Separators

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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

Legally Marketed Device under which Substantial Equivalence is Being Claimed

Fresenius Kabi is claiming the modified ALYX 2RBC-LR kit is substantially equivalent to and has the same intended use as the ALYX 2RBC-LR kit most recently cleared for market under BK200475 on 06/10/2020.

Device Description

The ALYX 2RBC-LR Kit is an apheresis kit designed for use with the ALYX instrument as part of the ALYX Component Collection System, which is a continuous-flow, centrifugal device system that separates whole blood into its components. The ALYX 2RBC-LR Kit is a sterile fluid path, single-use apheresis kit that consists of attached solutions, connectors, filter, and bags, for the collection of two leukoreduced red blood cell products by centrifugation.

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:

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- 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)

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- 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.

Technological Comparison as Compared to the Predicate Device

The technological characteristics of the proposed 2RBC-LR Kit remain the same as the predicate ALYX 2RBC-LR disposable kit. The proposed kit and predicate kit have the same performance characteristics and intended use. A modification to the 2RBC-LR Kit to enable the use of a functionally equivalent filter, subject of this 510(k), does not add, delete, or modify the technological characteristics of the disposable kit.

Modification to the Existing Device

This application is being submitted for a change to the leukoreduction filter component in the existing ALYX 2RBC-LR Kit. There are no other changes that are subject of this 510(k) application.

Performance Data

Testing was performed to demonstrate that the ALYX 2RBC-LR Kit with the alternate leukoreduction filter component meets existing specifications. The results of the testing were acceptable and demonstrate equivalence between the predicate kit and the proposed kit.

Clinical Data

Fresenius Kabi conducted a pivotal study to evaluate the equivalence of the new filter to that of the current ALYX 2RBC-LR kit filter for the indication of the ALYX 2RBC-LR collection procedure in adults.

Primary and secondary endpoint evaluations provided evidence that the efficacy of the alternate filter was substantially equivalent to the current filter.

Conclusion

The fundamental scientific technology, intended use, safety and effectiveness of the modified ALYX 2RBC-LR Kit remain unchanged. The verification testing performed and clinical study conducted in support of the change described in this application provide evidence that the proposed device is substantially equivalent to the predicate device.