Fresenius Kabi
Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

510(k) SUMMARY

Date Prepared

19 Mar 2020

Owner/Operator

Owner/ Operator# 9027285
Fresenius Kabi AG
Bad Homburg, Germany 61346

Contact Person (include full address, phone and fax numbers)

Submission Contact	Jody Stoughtenger
Title	Sr. Specialist, Regulatory Affairs
Address	Three Corporate Orive Lake Zurich, IL 60047
Phone	847 550 5689
Fax	847 550 2960
Email	jody.stoughtenger@fresenius-kabi.com
Official Correspondent	Cheryl Roscher
Title	Vice President, Regulatory Affairs
Address	Three Corporate Orive Lake Zurich, IL 60047
Phone	847 550 7909
Fax	847 550 2960
Email	cheryl.roscher@fresenius-kabi.com

Device Trade Name

ALYX Component Collection System

Common Name/Usual Name

Automated Blood Cell Separator / Centrifugal Separation Principle

Other Marketing Names

ALYX
ALYX System

Fresenius Kabi
Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

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 (Oocket 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 substantial equivalence with the ALYX Component Collection System most recently cleared for market under BK190351 on 06/04/2019. 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 BK190351 on 06/04/2019.

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 closed configurations. The cells are centrifugally separated within the kit by density differences.

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.

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

Fresenius Kabi
Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

- 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.

Fresenius Kabi
Three Corporate Drive
Lake Zurich, Illinois 60047
T 847-550-2300
T 888-391-6300
www.fresenius-kabi.us

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

Technological Comparison 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 include kits with components made with functionally equivalent materials from an alternate supplier, subject of this 510(k), does not add, delete, or modify the technological characteristics of the ALYX System or the disposable kits.

Modification to the Existing Device

This application is being submitted to address material changes in the existing ALYX Apheresis Kits. There are no other changes.

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 that include alternate supplier materials 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 activities performed in support of the changes described in this application provide evidence that the proposed device is substantially equivalent to the currently marketed device.