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510(k) SUMMARY

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Device Trade Name

AMICUS Separator System

Common Name/Usual Name:

Automated Separator, Blood Cell and Plasma, Therapeutic
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).

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Automated separators, used for separation of blood cells and plasma for therapeutic purposes, have not been classified under a regulation by the Center for Devices and Radiological Health due to pre-amendment status.

Product Code and Classification Panel

LKN (Gastroenterology/Urology panel) - Unclassified (due to pre-amendment status)
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 cleared AMICUS Separator System. The AMICUS Separator System is comprised of the AMICUS Separator instrument and a disposable AMICUS apheresis kit specific to the procedure being performed. The AMICUS Separator System was most recently cleared for market by CDRH under K200530 on September 11, 2020, and by CBER under BK170099 on October 10, 2017. The use of AMICUS Kits with a PAS connector was previously cleared under BK090065 (March 4, 2010) and the use of functionally closed AMICUS Platelet Kits was previously cleared under BK150288 (August 28, 2015).

Device Description

The AMICUS Separator System is comprised of the AMICUS Separator instrument and a disposable apheresis kit specific to the procedure being performed. The AMICUS Separator is a continuous-flow, centrifugal device that operates using pumps, clamps, and valves to move donor/patient blood through a single-use, sterile fluid path disposable kit. The Separator draws whole blood from a donor/patient, separates the blood into its components, collects one or more of the blood components, and returns the remainder of the blood components to the donor/patient. The cells are centrifugally separated within the kit by density differences.

The operator is responsible for connecting and monitoring the donor/patient and operating and monitoring the AMICUS Separator during the procedure. The operator controls the Separator through a touch screen. When necessary, the operator is alerted of problems with information on the screen and corresponding audible alerts.

Once the cell separation and collection is complete, the operator disconnects the donor/patient, removes the kit from the top panel of the Separator, and disposes of the kit per institutional SOPs. The kit is packaged in a recyclable plastic tray.

Statement of Intended Use

The AMICUS Separator System is an automated blood cell separator intended for use in the collection of blood components and mononuclear cells.

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The AMICUS Separator System is an automated blood cell separator intended for use in therapeutic apheresis applications and may be used to perform therapeutic plasma exchange (TPE).

The AMICUS Separator System is an automated blood component separator intended for use in therapeutic apheresis applications and may be used to perform red blood cell exchange, depletion, and depletion/exchange (RBCX) procedures.

Indications for Use

Depending on the AMICUS Separator System disposable used in the therapeutic apheresis procedure, the AMICUS Separator System has been cleared for the following:

The AMICUS Separator System is an automated blood cell separator indicated to perform therapeutic plasma exchange (TPE). (K111702)

The AMICUS Exchange Kit is indicated for use in therapeutic plasma exchange (TPE). The kit is for use with the AMICUS separator. (K111702)

The AMICUS Separator System is an automated blood component separator indicated to perform red blood cell exchange (RBCX), including exchange and depletion/exchange procedures, for the transfusion management of sickle cell disease in adults and children. (K180615)

The AMICUS Exchange Kit – Therapeutics is indicated for use in therapeutic plasma exchange (TPE) and red blood cell exchange (RBCX). The kit is for use with the AMICUS separator. (K111702, K180615)

The waste transfer set is indicated for use in red blood cell exchange (RBCX). The set is for use with the AMICUS separator. (K180615)

The Blood Component Filter Set with Vented Spike and Luer Adapter is indicated for the administration of blood and blood components during a therapeutic plasma exchange (TPE) or red blood cell exchange (RBCX) therapeutic apheresis procedure. The set is for use with the AMICUS separator. (K111702, K180615)

The AMICUS Separator System is an automated blood cell separator indicated for the collection of blood components and mononuclear cells.

Depending on the AMICUS Separator System apheresis kit used in the collection of products, the AMICUS Separator System has been cleared to collect:

Platelets Pheresis, Leukocytes Reduced (single, double, or triple units) (BK960005, BK990009)

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Platelets Pheresis, Leukocytes Reduced, Platelet Additive Solution (InterSol) (single, double, or triple units) (BK090065)

Red Blood Cells, Leukocytes Reduced (by apheresis) (BK000039)

Mononuclear Cells (BK000047)

Plasma (BK960005, BK120041)

- Fresh Frozen Plasma
  - Must be prepared and placed in a freezer at -18° C or colder within eight hours after phlebotomy.
- Plasma Frozen Within 24 Hours After Phlebotomy (PF24)
  - Must be stored at 1-6° C within eight 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 (PF24) 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.
- Source Plasma

The device is designed to collect products while maintaining an extracorporeal volume at or below 10.5 ml/kg and a donor post-platelet count greater than or equal to 100,000 platelets/microliter. (BK960005 and BK990009)

Platelets Pheresis (single, double, or triple units) may be manufactured from products that do not meet leukocyte reduction product standards. This does not apply to Platelet Pheresis, Platelet Additive Solution (InterSol) (single, double, or triple units). (BK990009 and BK090065)

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The AMICUS platelet storage container is cleared to store Platelets Pheresis, Leukocytes Reduced in 100% plasma for up to seven days. Additionally, for platelet units stored past five days and through seven days, every product must be tested with a bacterial device cleared by the FDA and labeled as a "safety measure." (BK050038 and BK150242)

Technological Comparison as Compared to the Predicate Device

The technological characteristics of the AMICUS Separator are standardized across procedures and remain the same as the predicate AMICUS Separator System. This includes the centrifuge system, separation technology, fluid control system, and anticoagulant management system which monitors and controls the delivery of anticoagulant solution based on operator parameters. The physical design of the AMICUS instrument includes three main areas of operation (touch screen, top panel, and centrifuge) that have the same technological characteristics as the predicate AMICUS device. There is also no change to the scientific technology or principles of operation of the AMICUS Separator System due to the introduction of the AMICUS SPIKESMART system for use with the new functionally closed kits. The data management capabilities of the AMICUS Separator are unchanged, and performance specifications are not impacted by AMICUS Software version 6.1.

The two new functionally closed disposable kits (4R2358 and 4R2359) do not introduce any new components or materials to the currently cleared AMICUS apheresis kit family. These kits are being created to offer a new kit configuration to customers and have no impact on the AMICUS Separator System fundamental technology and principles of operation.

Modification to the Existing Device

The primary change to the currently cleared AMCIUS apheresis kit family is the introduction of two new functionally closed apheresis kits with PAS spikes. Product labeling has been created for the new disposable kit product codes based on the currently cleared AMICUS apheresis kit labeling.

The primary change to the AMICUS Separator covered under this submission is the introduction of AMICUS Software version 6.1 and AMICUS SPIKESMART, intended to support the use of the new functionally closed kits. AMICUS Software version 6.1 includes a new "Functionally Closed Kit" feature with additional risk control measures for platelet collection procedures, and a new optional transfer state for the MNC collection procedure. AMICUS SPIKESMART includes a replacement saline hook component designed to be specifically compatible with certain saline containers. The purpose of the added software risk controls and AMICUS SPIKESMART is to further reduce the risk of the operator misconnecting solution containers to the incorrect lines during platelet collection procedures with a functionally closed kit. Additionally, the

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software has been updated to allow for an alternate MNC transfer state option. The purpose of this feature is to provide the customer with more flexibility and procedural control.

A new version of the currently cleared AMICUS Software version 6.0 Operator's Manual has also been created to include instructions for operation with the new Functionally Closed Kit feature. This version of the Operator's Manual is based on version 6.0 and is titled 6.1.

Performance Data

Performance testing and data submitted under previously cleared AMICUS Apheresis System filings remains valid for demonstrating performance of the AMICUS Separator System. Additional functional and performance testing was conducted to verify the use of the new functionally closed AMICUS apheresis kits with the AMICUS Software version 6.1 and SPIKESMART. Systems and software verification testing was also performed to demonstrate the functional equivalence of the proposed AMICUS Separator System device. The results of all verification testing demonstrate that the proposed AMICUS Separator System performs as intended in a safe and effective manner.

Conclusion

Based on the verification activities performed, the AMICUS Separator System modified with the new kit configurations, software version 6.1, and SPIKESMART, is substantially equivalent to the currently marketed AMICUS Separator System.