510(k) Summary

(Section 5)

510(k) Summary

5.1 Type of Submission: Traditional

5.2 Date of Summary: 11/25/2018

5.3 Submitter: PuriBlood Medical Co. Ltd.

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5.4 Identification of the Device:

Proprietary/Trade name:	Leukocyte reduction filter for red blood cells
Regulation Description:	Empty container for collection and processing of blood and blood components.
Review Panel:	General Hospital
Regulation Number:	864.9100
Device Class:	Class II
Product Code:	KSR

5.5 Identification of the Predicate Device:

Predicate Device Name:	Sepacell Pre-Storage Leukocyte Reduction Set For Red Cells
Original Applicant:	Baxter Healthcare Corporation Fenwal Division
Manufacturer::	Fresenius Kabi AG
Regulation number:	880.5440
Device Class:	Class II
Product Code:	CAK
510(k) Number:	BK980041

5.6 Intended Use

The Leukocyte Reduction Filter for CPDA-1 Red Blood Cells is indicated for the leukoreduction of a single unit of CPDA-1 Red Blood Cells collected from a blood donor and filtered within 8 hours when the red cells are stored at ambient temperature (20 to 24 °C), or not later than 7 days after collection when red cells are stored refrigerated at 1 to 6°C.

5.7 Device Description

Model number	Description
LRW-50-01-PS	Set length: 2,100 mm (82.68 inch) Tube Diameter: ID 3.0 mm/OD4.1 mm Drip chamber volume: 4 drops/mL Priming volume: 35 mL Sterile: Ethylene oxide (EtO), non-toxic and non-pyrogenic fluid path The product is assembled at the factory.
LRW-50-04-PS	Set length: 2,100 mm (82.68 inch) Tube Diameter: ID 3.0 mm/OD 4.1 mm Drip chamber volume: 4 drops/mL Priming volume: 35 mL Sterile: Ethylene oxide (EtO), non-toxic and non-pyrogenic fluid path The product is assembled at the factory.
LRW-50-05-PS	Set length: 2,200 mm (86.61 inch) Tube Diameter: ID 3.0 mm/OD 4.1 mm Drip chamber volume: 4 drops/mL Priming volume: 35 mL Sterile: Ethylene oxide (EtO), non-toxic and non-pyrogenic fluid path The product is assembled at the factory.
LRW-50-06-PS	Set length: 2,900 mm (114.17 inch) Tube Diameter: ID 3.0 mm/OD 4.1 mm Drip chamber volume: 4 drops/mL

Model number	Description
	Priming volume: 35 mL Sterile: Ethylene oxide (EtO), non-toxic and non-pyrogenic fluid path The product is assembled at the factory.
LRW-50-07-PS	Set length: 2,270 mm (89.37 inch) Tube Diameter: ID 3.0 mm/OD 4.1 mm Drip chamber volume: 4 drops/mL Priming volume: 35 mL Sterile: Ethylene oxide (EtO), non-toxic and non-pyrogenic fluid path The product is assembled at the factory.
LRW-50-08-PS	Set length: 1,830 mm (72.05 inch) Tube Diameter: ID 3.0 mm/OD4.1 mm Drip chamber volume: 4 drops/mL Priming volume: 35 mL Sterile: Ethylene oxide (EtO), non-toxic and non-pyrogenic fluid path The product is assembled at the factory.

5.8 Non-clinical Testing

A series of safety tests were performed to assess the safety and effectiveness of the Leukocyte reduction filter for red blood cells. All the test results demonstrate that Leukocyte Reduction Filter for Red Blood Cells meets the requirements of its pre-defined acceptance criteria and intended use.

- Sterilization Test
- Shelf life test
- Biocompatibility test
  - In Vitro Cytotoxicity Test
  - Intracutaneous Irritation Study in White Rabbit
  - Skin Sensitization Study in Guinea Pigs (Maximization Test)
  - Pyrogen Test in White Rabbits
  - Acute Intravenous Systemic Toxicity Study in Mice
  - Acute Intraperitoneal Systemic Toxicity Study in Mice
  - Hemolysis Test

Test results performed in biocompatibility test reports demonstrated that proposed device complies with ISO10993-1:2009, ISO10993-2:2006, ISO10993-4:2006, ISO10993-5:2009, ISO10993-10:2010, ISO10993-11:2006, ISO10993-12:2012, OECD404:2015, OECD406:1992, UPS39-NF34<87>:2016, UPS39-NF34<88>:2016, USP39-NF34<151>:2016, ASTM F619:2014, ASTM F750:2002 and ASTM F756:2014 requirements.

- Performance Test
  - Elemental analysis
  - Plasticizer content
  - Red blood cell viability testing
  - Red blood cell biochemical parameter

Bench test reports are conducted according to ISO3826-1:2013, ISO8536-4:2010 and USP 39-NF34<661.1>:2016.

5.9 Clinical Testing

No clinical test data were used to support the decision of substantial equivalence.

5.10 Substantial Equivalence Determination

The Leukocyte reduction filter for red blood cells has the similar intended use, material, components and performance data with the predicate device "Sepacell Pre-Storage Leukocyte Reduction Set For Red Cells" (BK980041). A series of tests were performed and demonstrated substantial equivalence between the proposed and the predicate device. Differences between the devices cited in this section do not raise any new issues of substantial equivalence.

Item	Proposed device	Predicate device	Substantially equivalent
Proprietary Name	Leukocyte reduction filter for red blood cells	Sepacell® Pre-Storage Leukocyte Reduction Set for Red Cells	-
510(k) Number	BK180188	BK980041	-
Product code	KSR	CAK	Same
Classification	II	II	Same
Intended Use	The Leukocyte Reduction Filter for CPDA-1 Red Blood Cells is indicated for the leukoreduction of a single unit of CPDA-1 Red Blood Cells collected from a blood donor and filtered within 8 hours when the red cells are stored at ambient temperature (20 to 24 °C), or not later than 7 days after collection when red cells are stored refrigerated at 1 to 6°C.	Leukocyte reduction of one unit of Red Blood Cells or Whole Blood.	Similar
Material	PVC, PC, PP, ABS and LDPE	PVC, PC, PP, ABS and LDPE	Same
Components	The set contains a filter, storage container(s) and associated tubings.	The set contains a filter, storage container(s) and associated tubings.	Same
Single use	Yes	Yes	Same
Sterile	Sterilized by Ethyleneoxide (EtO)	Sterilized by irradiation	Different

Item	Proposed device	Predicate device	Substantially equivalent
Performance data	Residual WBC: 2.3 x 10^5 cells/unit RBC Recovery: 90.5 %	The filtered product contains less than 5 x 10^6 residual WBC per unit and a post filtration RBC recovery of > 85%.	Similar
Design feature	Spike: Insert spike into the red cell unit Filter: Remove leukocyte Storage container: Storage leukoreduction blood	Spike: Insert spike into the red cell unit Blood Tubular filter: Remove blood clots Filter: Remove leukocyte Drip Chamber: Observe the flow rate Storage container: Storage leukoreduction blood	Similar

5.11 Similarity and Differences

The difference between the proposed device and predicate device is sterilization method. PuriBlood Medical Co. Ltd. has conducted the sterilize validation on the proposed device. The results have complied with the test requests. Therefore, the difference between the proposed and the predicate device did not raise any problem of substantial equivalence. The proposed device is substantially equivalent to the predicate device.

5.12 Conclusion

In conclusion, PuriBlood Medical Co. Ltd. believes that the “Leukocyte reduction filter for red blood cells” is substantially equivalent to the predicate device.