510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with 21 CFR §807.92.

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Trade Name:
PrepaCyte®-CB Processing System

Classification:
Class II
Cord blood processing system and storage container
21 CFR 864.9900

Product Code:
OAO

Predicate Device(s):
The subject device is equivalent to the following devices:

- PrepaCyte®-CB Processing System Model PCB150
- PrepaCyte®-CB Processing System Model PCB2100
- PrepaCyte®-CB Processing System Model PCB1100

Device Description:

- The PrepaCyte-CB Processing System is intended for single use and consists of a varying number of bags interconnected via tubing, with attached sterile ports and clamps. The first bag is the Cell Separation Media Bag which contains 150ml of PrepaCyte-CB separation media (reagent); the second is an empty bag for centrifugation of the leukocyte-rich supernatant; the third is a cryopreservation bag. An alternative model of the device includes only the Cell Separation Media Bag (first bag) containing 500 ml of PrepaCyte-CB Separation media that can be used to process up to 8 cord blood units using a transfer/freeze bag (not included).

Intended Use:

The PrepaCyte-CB Cord Blood Processing System is intended for use in cell processing laboratories to process and store total nucleated cells (TNC) from human umbilical cord blood prior to banking.

Brief Discussion of the Nonclinical Tests Submitted:
To verify that the device design met the functional and performance requirements, representative samples of the device underwent bench, biocompatibility, performance and user testing in accordance with the FDA Class II Special Controls Guidance Document: Cord Blood Processing System and Storage Container. These were cleared in the original 510(k) filing (BK070067). Additional laboratory testing was performed for the design and component changes being presented in this 510(k) notification to provide evidence that the changes made did not affect the safety or efficacy by making the proposed changes to the previously cleared device.

To summarize:

Testing of the new processing method was performed by Cryo-Cell to ensure that using PrepaCyte-CB as a multi-use did not introduce contamination risks, as well as ensure that the amount designated (60 ml per cord blood bag) did not change the functionality of the separation media. Validation was performed to confirm that this change does not affect the intended use of the device or alter the fundamental scientific technology of the device.

Results from testing of the new media showed that the changes to the media and process did not change the ability for cells to proliferate.

A hanging bag test demonstrated that the bags are able to withstand normal use.

Predicate Device Comparison Table

Table 1: Comparison to Predicate Device

	PrepaCyte-CB Processing System (Single-use bag) Predicate device	PrepaCyte CB Processing System (one-time use) (Multi-use media bag)	PrepaCyte-CB Processing System Reformulation
510(k) Number Decision Date	BK070067 December 17, 2008	TBD	TBD
Manufacturer	Cryo-Cell (previously BIO E)	Cryo-Cell	Cryo-Cell
Classification	II	II	II
Product Code	OAO	OAO	OAO
Regulation	21 CFR §864.9900	21 CFR §864.9900	21 CFR §864.9900
Indications for Use	The PrepaCyte-CB Cord Blood Processing System is a sterile, closed-bag processing system that easily and efficiently separates total nucleated cells (TNC) - including stem cells - from human umbilical cord blood prior to public or private banking.	The PrepaCyte-CB Cord Blood Processing System is intended for use in cell processing laboratories to process and store total nucleated cells (TNC) from human umbilical cord blood prior to banking.	The PrepaCyte-CB Cord Blood Processing System is intended for use in cell processing laboratories to process and store total nucleated cells (TNC) from human umbilical cord blood prior to banking.
Processing System Type	Manual closed system	Manual closed system	Manual closed system
Information About The Bag Sets			
Description of Models	5 models Four 3-bag configurations and one 1-bag configuration. The 3-bag models include a bag for cell separation, another for centrifugation and one for cryopreservation, all interconnected with tubing. Models: PCB1000, PCB1100, PCB2000, PCB2100, and PCB150	1 model One multi-use bag of 500ml PrepaCyte-CB media that can be used to process up to 8 cord bloods within one processing event, and must utilize a transfer bag set. Model: PCB500	3 models • PCB1100 is a 3 bag set with 150 ml of PrepaCyte-CB media • PCB2100-270 (Previously PCB2100) is a 2 bag set with 150 ml of PrepaCyte-CB media • PCB500 (previously PCB150) is a 1 bag of 500ml PrepaCyte-CB media Cryo-Cell has stopped manufacturing models PCB1000 and PCB2000
DMSO filter included in system	No	No	No

Table 1: Comparison to Predicate Device

	PrepaCyte-CB Processing System (Single-use bag) Predicate device	PrepaCyte CB Processing System (one-time use) (Multi-use media bag)	PrepaCyte-CB Processing System Reformulation
Materials	Bag 1 - EVA film Bag 2 - EVA film Cryo Bag (Bag 3) – EVA Tubing - EVA/PVA and PVC	Bag – EVA film	Bag 1 - EVA film Bag 2 - EVA film Cryo Bag (Bag 3) – EVA Tubing - EVA/PVA and PVC
Sterilization Method	Bag set Gamma sterilized PrepaCyte-CB separation media aseptically filled into Bag 1	Bag set Gamma sterilized PrepaCyte-CB separation media aseptically filled into a 500ml multi-use bag.	Bag set Gamma sterilized PrepaCyte-CB separation media aseptically filled into Bag 1
Non-pyrogenic	Yes	Yes	Yes
Bag Set Shelf-Life	12 months	12 months	12 months
Separation Media	Supplied PrepaCyte-CB Separation Media supplied prefilled in Bag 1 of the bag set.	Supplied PrepaCyte-CB Separation Media supplied as 500ml bag.	Supplied PrepaCyte-CB Separation Media supplied prefilled in Bag 1 of the bag set.
Packaging	Bag sets individually packaged in a nylon laminate pouch; packaged 20/box	Bag sets individually packaged in a nylon laminate pouch; packaged 20/box	Bag sets individually packaged in a nylon laminate pouch; packaged 20/box
Processing System Performance Data			
Processing time	63 – 80 minutes (clinical study results)	63 – 80 minutes (clinical study results)	63 – 80 minutes (clinical study results)
Cord Blood Volume	65 (raw cord blood) - 200 mL (w/ anticoagulant)	65 (raw cord blood) - 200 mL (w/ anticoagulant)	65 (raw cord blood) - 200 mL (w/ anticoagulant)
Freeze Volume	Model PCB2000 series 24 – 26 mL Model PCB1000 24 – 27 mL Model PCB1100 10 – 25 mL	24-26 mL	24-26 mL
TNC Recovery	87.4% (adjusted to exclude nRBCs)	84.6% (adjusted to exclude nRBCs)	84.6% (adjusted to exclude nRBCs)
CD34+ Viability	94.9%	97%	97%
RBC Depletion	98.5%	98.4%	98.4%

Conclusion:

Cryo-Cell International, Inc. considers the PrepaCyte-CB Processing System to be equivalent to their predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use. The intended use of the modified device, as described in the labeling, has not changed as a result of the modifications.