510(k) Summary (Special 510(k))

OriGen Cryostore Multi-Chamber Freezing Bags

BK180278

1. Submission Sponsor

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3. Date Prepared

27 September 2018

4. Device Identification

Trade/Proprietary Name: OriGen Cryostore Multi-Chamber Freezing Bags

Common/Usual Name: Empty container for the collection and processing of blood and blood components

Regulation Number: 864.9100

Product Code: KSR, Container, Empty, For Collection & Processing Of Blood & Blood Components

Device Class: Class II

Classification Panel: Hematology

5. Legally Marketed Predicate Device(s)

BK030036, OriGen Cryostore Freezing Bags

6. Indication for Use Statement

The Cryostore bag is designed to cryogenically freeze blood components. This product is for single use only, contraindicated for other uses. Contains no Phthalates, BPA or latex.

7. Device Description

The OriGen Cryostore Multi-Chamber Freezing Bags are a safe, economical way to preserve blood components when cryopreservation is indicated. The Multi-Chamber bags are made from Ethylene Vinyl Acetate (EVA) film and resin, which combines tough, low temperature durability with excellent clarity, flexibility, impact and puncture resistance. EVA has good vapor and gas barrier properties, helping to reduce sample contamination. The EVA material is biologically inert which will keep the stored cells in an unaltered environment. With its combination of strength and flexibility, the Multi-Chamber bag is very well suited for centrifugation. The Multi-Chamber bags have multiple chambers that can be filled from a single location and the channel located at the bottom of the bag allows for heat sealing between each chamber. The individual chambers can be sealed and separated to allow for multiple post thaw applications without compromising the integrity of the rest of the cellular product.

8. Substantial Equivalence Discussion

The following table compares the OriGen Cryostore Multi-Chamber Freezing Bags to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	**OriGen Biomedical, Inc.**	**OriGen Biomedical, Inc.**	**Device Comparison**
Trade Name	**OriGen Cyrostore Freezing Bags**	**OriGen Crytostore Multi-Chamber Freezing Bags**	
510(k) Number	BK030036	BK180278	Same
Product Code	KSR	KSR	Same

Manufacturer	OriGen Biomedical, Inc.	OriGen Biomedical, Inc.	Device Comparison
Trade Name	**OriGen Cyrostore Freezing Bags**	**OriGen Crytostore Multi-Chamber Freezing Bags**	
Regulation Number	864.9100	864.9100	Same
Regulation Name	Container, Empty, For Collection & Processing Of Blood & Blood Components	Container, Empty, For Collection & Processing Of Blood & Blood Components	Same
Indications for Use	The OriGen Cryostore Freezing bag is intended to be used for blood component freezing. The device is for single use only.	The CryoStore bag is designed to cryogenically freeze blood components. This product is for single use only, contraindicated for other uses.	Same
Mechanism of Action	Preservation of blood components during cryopreservation via the physio-chemical properties of the device at sub-zero temperatures.	Preservation of blood components during cryopreservation via the physio-chemical properties of the device at sub-zero temperatures.	Same
Technology Overview	Single chamber that can be filled from a single location. Comes in variants categorized by bag or chamber size, attached tubing sets, and packaging configurations. Shape and orientation of the chambers and bags may vary. Device is terminated with a tube set comprised of a combination of tubing, luer connections, bag spikes, valves, stopcocks, empty syringes, and other molded	Multiple chambers that can be filled from a single location and channel located at the bottom of bags allows for heat sealing between each chamber. The individual chambers can be sealed and separated to allow for multiple post thaw applications without compromising the integrity of the rest of the cellular product. Comes in variants categorized by bag or chamber size, attached tubing sets, and packaging configurations.	Partially different; the change in the number of chambers raises no new questions safety and effectiveness as compared to the predicate as demonstrated by testing that shows compliance with the same standards / performance specifications.

Manufacturer	OriGen Biomedical, Inc.	OriGen Biomedical, Inc.	Device Comparison
Trade Name	**OriGen Cyrostore Freezing Bags**	**OriGen Crytostore Multi-Chamber Freezing Bags**	
	components. Variant tube sets may be designed per customer request to suit the specific connection needs of the user.	Shape and orientation of the chambers and bags may vary but all chambers present on a single freezing bag are integrally connected. Device is terminated with a tube set comprised of a combination of tubing, luer connections, bag spiked, valves, stopcocks, empty syringes, and other molded components. Variant tube sets may be designed per customer request to suit the specific connection needs of the user.	
Anatomical Location	External communicating device (Blood path, indirect)	External communicating device (Blood path, indirect)	Same
Materials	Ethyl vinyl acetate (EVA) (Parts: Bag film, donor tube, spike ports, bag shells, Needle-free Valve)	Ethyl vinyl acetate (EVA) (Parts: Bag film, donor tube, spike ports, bag shells) Cyclo-olefin polymer (COP) (Parts: Needle-free Valve)	Partially different; the change in the materials raises no new questions of safety and effectiveness as compared to the predicate as the different material is USP Class VI.
Material (Accessories)	Acrylonitrile butadiene styrene (ABS), Polyvinyl Chloride (PVC), Polystyrene, Polyethylene, Acrylic, Eastar MN 004 Polymer, Polypropylene (Tube sets)	Acrylonitrile butadiene styrene (ABS), Polyvinyl Chloride (PVC), Polystyrene, Polyethylene, Acrylic, Eastar MN 004 Polymer, Polypropylene, Nylon (Tube sets)	Partially different; the change in the materials raises no new questions of safety and effectiveness as compared to the predicate as the different material is USP Class VI.

Manufacturer	OriGen Biomedical, Inc.	OriGen Biomedical, Inc.	Device Comparison
Trade Name	**OriGen Cyrostore Freezing Bags**	**OriGen Crytostore Multi-Chamber Freezing Bags**	
Sterile	Yes (Irradiation)	Yes (Irradiation)	Same
Single-Use	Yes	Yes	Same
Shelf Life	4 years	4 years	Same
Complies with ISO 10993-1	Yes	Yes	Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of OriGen Cryostore Multi-Chamber Freezing Bags and in showing substantial equivalence to the predicate device, OriGen Biomedical, Inc. completed a number of non-clinical performance tests in accordance with design control requirements (21 CFR 820.30). The OriGen Cryostore Multi-Chamber Freezing Bags meets all the requirements for overall design, sterilization, and performance confirming that the design output meets the design inputs and specifications for the device.

Testing was performed to address the hazards identified in risk analyses performed by OriGen Biomedical, Inc related to the OriGen Cryostore Multi-Chamber Freezing Bags.

The OriGen Cryostore Multi-Chamber Freezing Bags passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Sterilization testing per ISO 11137-1; ISO 11137-2; ISO 11137-1; ISO 11137-2; ISO 11607-1; ISO 11607-2; ANSI AAMI ST72; USP 40-NF 35 <85>
- Labeling per ISO 15223-1
- Physical testing per ISO 3826-1; ISO 80369-1; USP 40-NF35 <661>

10. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

The OriGen Cryostore Multi-Chamber Freezing Bags, as modified, is determined to be substantially equivalent to the unmodified predicate device.