

510(k) Summary

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Date Prepared: January 12, 2010

Device Nomenclature:

Trade Name(s): CryoMACS[®] Freezing Bag 50,
CryoMACS[®] Freezing Bag 250,
CryoMACS[®] Freezing Bag 500,
CryoMACS[®] Freezing Bag 750 and
CryoMACS[®] Freezing Bag 1000

Common Name: Freezing Bag

Classification Name: Frozen donor tissue storage container (Unclassified, Product Code LPZ)

Predicate Devices

Primary: Baxter Cryocyte[™] Freezing Container (BK950049)

Secondary: Charter Medical Cell Freeze[™] Liquid Nitrogen Freezing Container (BK060042)

Device Description: The CryoMACS[®] Freezing Bags are single use only, sterile (by irradiation), containers intended for a single cycle of freezing, storage (down to -196°C), and subsequent thawing (at 37°C) of hematopoietic progenitor cells. The CryoMACS[®] Freezing Bags are comprised of a freezing bag (with access ports) as the primary containment for the hematopoietic progenitor cells and an overwrap bag as secondary containment. They have an integrated tubing set (Filling Assembly) containing an injection port and male and female luer lock assemblies which provide flexibility to use a variety of disposable transfer sets, syringes or Sterile Connecting Device (SCD[®]) for aseptic processing. Additionally, the CryoMACS[®] Freezing Bags have a built-in label pocket which allows the insertion of written information such as patient identification and product specifications for hematopoietic progenitor cells, volume and processing methods used. As part of the bag assembly, two spike ports are available which allow access to the bag contents for therapeutic use of the product (via attachment of a sterile transfusion assembly).

Intended Use: The CryoMACS[®] Freezing Bag are intended for a single cycle of freezing, storage (down to -196°C), and subsequent thawing (at 37°C) of hematopoietic progenitor cells.

The indication for use is functionally equivalent to the predicate device(s), Baxter Cryocyte[™] and Charter Medical Cell Freeze[™] Liquid Nitrogen Freezing Containers.

Technological

Characteristics: The CryoMACS[®] Freezing Bags are substantially equivalent in intended use, design, technology/principal of operation, materials and performance to the Baxter Cryocyte[™] Freezing Container and Charter Medical Cell Freeze[™] Liquid Nitrogen Freezing Containers. Differences between the devices do not raise any significant issues of safety and effectiveness.

Table 1: Comparison to Predicate Devices			
	CryoMACS[®] Freezing Bag	Cryocyte[™] Freezing Container	Charter Medical Cell Freeze[™] Liquid Nitrogen Freezing Container
Intended use	The CryoMACS [®] Freezing Bag is intended for single cycle of freezing, storage (down to -196°C), and subsequent thawing (at 37°C) of hematopoietic progenitor cells.	Cryocyte [™] freezing container is intended to be used for blood component freezing.	Charter Medical Cell Freeze [™] Liquid Nitrogen Freezing Container is intended for the storage, preservation and transfer of peripherally derived stem cells, in liquid nitrogen to -196°C
Specimen	Hematopoietic progenitor cells	Blood components	peripherally derived stem cells
Materials	Ethyl vinyl acetate (EVA)	Ethyl vinyl acetate (EVA)	Polyolefin
Design	A sterile EVA freezing bag with label pocket, 2 membrane ports and integrated tubing set with 1 injection site, 1 male and 2 female luer lock adapters and 3 roller clamps	A sterile EVA plastic container with label pocket, 2 sealed membrane ports and integrated tubing set with 1 injection site, 1 male and 2 female luer lock adapters and 3 roller clamps	A sterile polyolefin elastomer bag with attached tubing segments with standard connections used in blood storage container systems.
Capacity	10-20 mL, 30-70 mL, 55-100 mL, 80-190 mL and 125-270 mL	10-20 mL, 30-70 mL, 55-100 mL, 80-190 mL and 125-270 mL	30-60 mL, 50-90 mL, 55-100 mL, and 70-120 mL

Nonclinical

Performance Data: Verification of device performance was established with acceptable results from the following non-clinical tests: biocompatibility, durability in freeze/thaw studies in liquid nitrogen, clinical-use simulation including freeze/thaw studies with cell viability testing, DMSO extractable substances, particulate matter determination and the effects of disinfectants on bag integrity

Conclusion: It is the conclusion of Miltenyi Biotec Inc., that the CryoMACS[®] Freezing Bags, 50, 250, 500, 750 and 1000, are substantially equivalent to, and as safe and effective as, the predicate device(s).