

Special 510(k)

510(k) Summary

510(k) Owner: Biowy Corporation
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Device name:
Trade name: Biowy Multi-Chamber Freezing Bag Set
Common Name: Freezing Bag
Classification name: Container, Frozen Donor Tissue Storage
FDA Product Code: LPZ
Classification: Unclassified

Predicate Device: Biowy Multi-Chamber Freezing Bag (BK251308)

Device Description: The Biowy multi-chamber freezing bag set is a sterile plastic flexible container intended only for a single sequence of freezing, storage (in Liquid Nitrogen (-196°C)), and subsequent thawing (at +37°C) of hematopoietic progenitor cells. The freezing bag product is comprised of a multi-chamber freezing bag with twist-off ports, extension tubing and connectors with a transfer/process bag and a supernatant collecting bag.

Indications for Use: The Biowy Freezing Bag Set is intended for a single sequence of freezing, storage (in Liquid Nitrogen (-196°C)), and subsequent thawing (at +37°C) of hematopoietic progenitor cells.

Technical Characteristics

The Biowy Multi-Chamber Freezing Bag Set is substantially equivalent to the predicate in indications for use, design, technology/principal of operation, materials and performance. Differences between the devices do not raise any significant issues of safety and effectiveness.

	Predicate	Subject Device
	Biowy Multi-Chamber Freezing Bag (BK251308)	Biowy Multi-Chamber Freezing Bag Set
Indications for Use	The Biowy Freezing Bags are intended for a single sequence of freezing, storage (in Liquid Nitrogen (-196°C)), and subsequent thawing (at +37°C) of hematopoietic progenitor cells.	The Biowy Multi-Chamber Freezing Bags are intended for a single sequence of freezing, storage (in Liquid Nitrogen (-196°C)), and subsequent thawing (at +37°C) of hematopoietic progenitor cells.
Specimen	Hematopoietic progenitor cells	Same as the predicate
Materials	Freezing bag: EVA	Freezing bag: EVA (same as the predicate)

	Accessory bag: Mixing bag (EVA) Extension tubing/connectors: PVC, ABS, PP	Accessory bags: Transfer/process bag and supernatant collecting bag (PVC, different from the predicate) Extension tubing/connectors: PVC, ABS, PP (same as the predicate)
Design	A sterile multi-chamber EVA freezing bag with integrated tubing and a mixing bag.	A sterile multi-chamber EVA freezing bag with integrated tubing, a transfer/process bag and a supernatant collecting bag.
Freeze capacity	10-35ml	10-35ml

**Nonclinical
Performance
Data:**

Verification of device performance was established with acceptable results from the following non-clinical tests: mechanical strength, biocompatibility, durability in freeze/thaw studies in liquid nitrogen.

Conclusions:

The Biowy Multi-Chamber Freezing Bag Set is substantially equivalent to the predicate device.