

BK170150 510(k) Summary

510(k) Owner: Biowy Corporation
27031 Vista Terrace
Lake Forest, California 92630

Primary Contact: Andre von Muller
RA/QA Manager
Biowy Corporation
Telephone: 1-949-305-8211
Fax: 1-866-506-5094
Email: Avonmuller@biowy.com

Date prepared: May 2, 2018

Device name:
Trade name: Biowy Freezing Bags
Common Name: Container, Frozen Donor Tissue Storage
FDA Product Code: LPZ
Classification: Unclassified

Predicate Device: Miltenyi Biotec CryoMACS Freezing Bags (BK090020)

Device Description: The Biowy Freezing Bags are a single sequence only, sterile container intended 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 freezing bag with an access tubing and tear-off ports. The access tube is extended with extension tubing that has female luer lock which allows fluid transfer in with a variety of devices such as syringe, transfer set and connecting device. The tear-off ports allow fluid transfer out via a spike device. Next to the fluid containing area, the bag has a label pocket which allows the insertion of sample information or patient information card. Additionally, each bag has a series identification number in coded in the labeling area for facilitating identification.

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.

Technical Characteristics: The Biowy Freezing Bags are substantially equivalent in intended use, design, technology/principal of operation, materials, and performance to the Miltenyi Biotec CryoMACS Freezing Bags. Differences between the devices do not raise any significant issues of safety and effectiveness.

Table 1 Comparison to Predicate Device

	Proposed Device: Biowy Freezing Bags	Predicate: Miltenyi Biotec CryoMACS Freezing Bag
Intended 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 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.
Specimen	Hematopoietic progenitor cells	Hematopoietic progenitor cells
Materials	Ethylene vinyl acetate (EVA) polymer	Polyolefin (EVA)
Design	A sterile EVA freezing bag with a label pocket, one or two membrane ports and integrated tubing set with two female luer lock connectors and two pinch clamps.	A sterile EVA freezing bag with a label pocket, two membrane ports and integrated tubing set with an injection site, one male and two female luer lock connectors and three roller clamps.
Capacity	10-30ml, 30-70ml, 55-100ml, 120-275ml	10-20ml, 30-70ml, 55-100ml, 80-190ml, 125-270ml

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, and freeze/thaw testing in clinical-simulation use.

Test	Results
Capacity volume	Passed
Transfer in	Passed
Emptying	Passed
Tubing-bag strength	Passed
Port sealing	Passed
Suspension	Passed
Seal strength (leak)	Passed
Drop strength	Passed
Freeze/Thaw	Passed
Multiple Freeze/Thaw cycles10x	Met Requirements
Chemical Analysis	Met Requirements
Leachable	Met Requirements
Particulate contamination	Met Requirements
Sterility	Met Requirements
Biocompatibility	Met Requirements
Cell Viability and Recovery	Met Requirements
Distribution Studies (including Shelf Life)	Met Requirements

Conclusions: Thus, the Biowy Freezing Bags are substantially equivalent to, and are as safe and effective as, the predicate device.