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510(k) Summary

Charter Medical Cell Freeze™ Liquid Nitrogen Freezing Container

510(k) Owner:

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Device Nomenclature:

Trade Name: Cell-Freeze® Liquid Nitrogen Freezing Container
Common Name: Freezing Bag
Classification Name: Empty Container for the Collection and Processing of Blood and Blood Components (21 CFR 864.9100, Code KSR)

Predicate Devices:

1. Baxter Cryocyte™ Freezing Container (BK950049)
2. Origen Cryostore Freezing Bag (BK030036)

Device Description:

The Cell-Freeze® Liquid Nitrogen Freezing Container product is a bag with attached tubing segments offered with maximum filling capacities of 60 mL, 90 mL, and 125 mL. The container will be manufactured using polyolefin elastomer film. The product will also consist of Ethylene Vinyl Acetate (EVA) and Poly Vinyl Chloride (PVC) tubing segments with standard connections used in blood storage container systems.

The device is provided sterile fluid path and intended for single use.

Intended Use:

The 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. The Cell-Freeze® Liquid Nitrogen Freezing Container is provided sterile fluid path and intended for single use.

These indications for use are functionally equivalent to the predicate devices listed above.

Technological Characteristics:

The function, design and construction of the Cell-Freeze® device and the predicate devices are analogous. The containers are manufactured from differing materials.

Table 1

	Baxter Cryocyte™ Freezing Container (BK950049)	Origen Cryostore Freezing Bag (BK030036)	Charter Medical Cell-Freeze® Liquid Nitrogen Freezing Container
Material	Ethyl vinyl acetate (EVA)	Ethyl vinyl acetate (EVA)	Polyolefin

Functionally, the differing film materials perform equivalently. The polyolefin film performs adequately at -196°C, as evidenced by performance testing.

The capacity specifications for the containers vary by manufacturer.

Table 2

	Baxter Cryocyte™ Freezing Container (BK950049)	Origen Cryostore Freezing Bag (BK030036)	Charter Medical Cell-Freeze® Liquid Nitrogen Freezing Container
Capacity	10-20 ml, 30-70 ml, 55-100 ml, 80-190 ml	10-20 ml, 30-70 ml, 55-100 ml, 80-190 ml	30-60 ml, 50-90ml, 70-125 ml

The capacity of the Cell-Freeze® device is within the range of the predicate devices.

Nonclinical Performance Data:

Verification of device performance was established through the following non-clinical tests with acceptable results: biocompatibility, durability in liquid nitrogen, cell viability post freeze/thaw, sterility/microbial challenge, physical performance testing of film, drop testing and stability study for shelf life of post sterile dry bag.

Conclusion:

It is the conclusion of Charter Medical that the Cell-Freeze® Liquid Nitrogen Storage Container is substantially equivalent to and as safe and effective as the predicate devices.