

B11030036

# OriGen

BIOMEDICAL

**510(k) Summary**  
**OriGen Cryostore Freezing bags**

May 22, 2003

Common Name: Freezing Bag, Classification KSR

Classification Name: Container, empty, for collection & processing of blood & blood components  
(per 21CFR 864.9100)

The OriGen Cryostore Freezing bag is intended to be used for blood component freezing. The device is for single use only. It is functionally equivalent to the Baxter Cryocyte bag approved under K780354.

The function, materials and construction of the devices are nearly identical. Performance testing included biocompatibility testing, thermal shock, durability in liquid nitrogen, and stability after sterilization. OriGen has concluded that the Cryostore freezing bag is durable and at least as safe and effective as the predicate device. This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Sincerely,



Richard Martin  
President