

BK 980041

510(k) Summary of Safety and Effectiveness

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Trade/Proprietary Name of Device: Sepacell® Pre-Storage Leukocyte Reduction Set for Red Cells

Common or Usual Name of Device: Red Blood Cell Filter for Leukocyte Removal

Classification Name of Device: Microfilter, Blood Transfusion
(21 CFR 880.5440)

Legally Marketed Device Under Which Substantial Equivalence is being Claimed: Sepacell ® Pre-Storage Leukocyte Depletion Set for Red Cells, cleared for market entry under 510(k) BK920032 on June 7, 1993.

Device Description: The set contains a filter, storage container(s), and associated tubings. It can be used for pre-storage leukoreduction of red blood cell products.

Intended Use of Device: Leukocyte reduction of one unit of Red Blood Cells or Whole Blood.

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*Comparison of Technical
Characteristics of the Device vs.
the Predicate Device:*

The product is substantially equivalent to the predicate device with regard to its design, material, methods of sterilization, and intended use. The leukoreduction processing window for one unit of Red Blood Cells is now allowed after 2 hours of refrigeration up to outdate.

*Brief Discussion of Tests and
Their Results Submitted in the
Application:*

The Sepacell® Pre-storage Leukocyte Reduction Set for Red Cells with an R-500(II) filter was evaluated in a laboratory study which measured filter performance and *in vitro* red cell indices when AS-1 Red Blood Cells were leukoreduced after 2 hours, 1 day, 15-20 days, and 35-42 days of refrigerated storage. The filtered product contains less than 5×10^6 residual WBC per unit and a post filtration RBC recovery of > 85%. Acceptable RBC parameters were found in all units both at the time of post filtration and through out 42 days storage. Acceptable RBC parameters were also obtained from aliquots of leukoreduced CPDA-1 and AS-1 RBC's stored for 35 or 42 days, respectively, in 150 mL containers.

*Conclusions Drawn for the in
vitro study that demonstrate that
the Device is Safe, Effective, and
Performs As Well As or Better
than the Predicate Device:*

Based on the data from this *in vitro* study, it is concluded that the Sepacell® Pre-Storage Leukocyte Reduction Set for Red Cells is safe and effective. Leukoreduction after 2 hours of refrigeration up to out date of Red Blood Cells provides acceptable red cells for transfusion.