

### 510(k) Summary of Safety and Effectiveness

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*Trade/Proprietary Name of Device:* LeukoConnect – Pre-Storage Sterile  
Connect Leukoreduction Set with Sepacell  
Filter for Red Blood Cells

*Common or Usual Name of Device:* Leukocyte Reduction Filter Set

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

*Legally Marketed Device Under  
Which Substantial Equivalence  
is Claimed:* Pre-Storage Leukocyte Reduction Set  
for Red Cells cleared for market entry under  
510(k) BK980041

*Device Description:* The LeukoConnect – Pre-Storage Sterile  
Connect Leukoreduction Set with Sepacell  
Filter for Red Blood Cells contains a  
Sepacell RS-2000 Filter, a PVC storage  
container and associated tubings,  
connectors, clamps, and a one-way valve.  
The set can be sterile connected to a unit of  
Red Blood Cells for pre-storage  
leukoreduction. The leukoreduced Red  
Blood Cells may then be stored for the  
maximum dating period before transfusion.

*Intended Use of Device:*

The LeukoConnect – Pre-Storage Sterile Connect Leukoreduction Set with Sepacell Filter for Red Blood Cells is intended for leukoreduction of one unit of Red Blood Cells in additive solution at ambient temperature within 8 hours after blood collection, or at refrigerated temperature within 72 hours after blood collection. The filtered red cells may then be stored for the maximum dating period before transfusion.

*Comparison of Technological Characteristics of the Device vs. A Legally Marketed 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 in additive solution is now up to 8 hours at ambient temperature, or up to 72 hours at refrigerated temperature after blood collection.

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

The LeukoConnect – Pre-Storage Sterile Connect Leukoreduction Set with Sepacell Filter for Red Blood Cells was evaluated in a laboratory study which measured filter performance and *in vitro* red cell indices when AS-1 Red Blood Cells were leukoreduced within 72 hours after blood collection. The study results demonstrated that the LeukoConnect RBC filter set can be used effectively to produce AS-1 Red Blood Cells, Leukocytes Reduced, with a residual WBC count of  $< 5 \times 10^6$  per unit, and a post filtration RBC recovery of  $\geq 85\%$ . Acceptable RBC parameters were found in all units both at the time of post filtration and through out 42 days storage. Hemolysis values from end of storage at 42 days were all  $< 1\%$ .

*Conclusions Drawn from the  
In Vitro Study that Demonstrate that  
The Device is Safe, Effective, and Performs  
As Well As or Better than the Legally  
Marketed Device:*

Based on the data generated from the *in vitro* study, it is concluded that the LeukoConnect – Pre-Storage Sterile Connect Leukoreduction Set with Sepacell Filter for Red Blood Cells is safe and effective. Leukoreduction of Red Blood Cells in additive solutions within 72 hours after blood collection provides acceptable red cells for transfusion.

  
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