

510(k) Summary
for
HemaSure r\LS™ Pre-Storage Leukoreduction Filtration System
for Red Blood Cells

SPONSOR/MANUFACTURER

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DEVICE NAME

Proprietary Name: HemaSure r\LS™ Pre-Storage Leukoreduction Filtration System for Red Blood Cells; and
HemaSure r\LS™ Pre-Storage Leukoreduction Filtration System with Spike for Red Blood Cells

Common/Usual Name: Leukocyte Reduction Filter System for Red Blood Cells

Classification Name: Blood Transfusion Microfilter

PREDICATE DEVICES

- Pall BPF4 High Efficiency Leukocyte Removal Blood Processing Filter System
Pall Biomedical Products Corporation
BK910019

- Fenwal Sepacell Pre-Storage Leukocyte Depletion Set for Red Cells
Baxter Healthcare Corporation
BK920032
- LeukoNet™ Pre-Storage Leukoreduction Filtration System
HemaSure Inc.
BK950008

DEVICE DESCRIPTION

The major components of the HemaSure r\LS Pre-Storage Leukoreduction Filtration System for Red Blood Cells are a filter assembly, tubing, a RBC storage bag and an air removal bag. The filter assembly contains filtration media for leukocyte reduction. All tubing is medical grade polyvinyl chloride (PVC) and meets the requirements of the system to sterile dock to the primary bag using an FDA approved or cleared sterile connecting device. The RBC storage bag is made of medical grade PVC and holds a maximum volume of 600 ml.

The HemaSure r\LS Filtration System is connected to the RBC primary bag by sterile docking or by spike. The r\LS is a gravity-driven filtration system which achieves automatic priming and filtration without mechanical means.

INTENDED USE

The HemaSure r\LS Pre-Storage Leukoreduction Filtration System for Red Blood Cells is a single use device that removes leukocytes from a single unit of Red Blood Cells prior to storage. The fluid pathway is sterile and non-pyrogenic. The system includes a filter, attached tubing and a storage bag, and is available with a Spike. The HemaSure r\LS Filtration System is intended for blood bank use with a Sterile Connecting Device (closed system processing) or with a Spike (open system processing).

The HemaSure r\LS Filtration System is indicated for leukoreduction of a single unit of Red Blood Cells up to 7 days after collection. Filtered Red Blood Cells may be stored for the period of time appropriate for the anticoagulant and preservative used. Use of the Spike requires the leukocyte reduced Red Blood Cells to be stored at 1-6°C and transfused within 24 hours.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The HemaSure r\LS Pre-Storage Leukoreduction Filtration System for Red Blood Cells is substantially equivalent in intended use and function to legally marketed filtration systems for the pre-storage reduction of leukocytes in Red Blood Cells, specifically including the predicate devices cited above. In particular, the HemaSure r\LS Filtration System is constructed of similar materials and has similar characteristics for leukoreduction efficiency and recovery of red blood cells as the predicate devices.

7. PERFORMANCE TESTING

Biological Evaluation and Chemical Testing: Testing was conducted in accordance with applicable guidelines of ISO 10993, Biological Evaluation of Medical Devices and ISO 3826, Plastic Collapsible Containers for Human Blood and Blood Components. Tests were performed on key components of the HemaSure r\LS Filtration System and on the finished device. Materials evaluated passed all biological and chemical testing performed.

Nonclinical Testing: Performance of the HemaSure r\LS Filtration System was evaluated in two separate types of nonclinical studies. One study examined product performance based on an assessment of WBC residuals, RBC recovery, and filtration time. The other study also included these product performance measures as well as storage stability parameters following filtration and storage throughout standard retention periods. Results of these studies indicated that the HemaSure r\LS Filtration System met applicable guidelines for pre-storage leukoreduction and that there were no significant differences in hematology parameters for red cell function between the filtered and non-filtered red blood cells.

Clinical Testing: Clinical studies were performed at two investigational sites under Institutional Review Board approval. These studies evaluated filtration performance as well as in vitro storage stability and in vivo survival of red blood cells. Autologous comparisons of non-filtered controls were made to filtrations performed with the HemaSure r\LS Filtration System. The results of these clinical studies showed average in vivo RBC recovery above 75% and average hemolysis below 1% after 42-day storage. No adverse effects were shown on filtered and stored red blood cells.