510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Date Prepared: September 3, 2008

Sponsor: HEMERUS Medical, LLC
5000 Township Parkway
Saint Paul, MN 55110

Contact: Lynn Jensen
HEMERUS Medical, LLC
Regulatory Affairs / Quality Assurance
5000 Township Parkway
Saint Paul, MN 55110
(Ph) 651-635-0070
(Fx) 651-635-0090

Device Name: HEMERUS LEUKOSEP® HRC-600-C Leukocyte Reduction Filtration System for Red Blood Cells

Common Name: Microfilter, Blood Transfusion

Product Code: CAK

Class: Class II

Regulation Number: 21CFR 880.5440

Indications for Use:
The LEUKOSEP® HRC-600-C Leukocyte Reduction Filtration System for Red Blood Cells is indicated for pre-storage leukoreduction of a single unit of CPD/AS-1 Red Blood Cells.

- AS-1 Red Blood Cells processed and filtered at room temperature within 8 hours after blood collection, then stored as AS-1 Red Blood Cells, Leukocytes Reduced at 1-6 °C within 8 hours.
- Whole blood stored at 1-6 °C within 8 hours after blood collection. Red Blood Cells prepared and AS-1 added within 48 hours of collection. Leukocyte Reduction filtration initiated no later than Day 3 after collection.

Filtered Red Blood Cells may be stored for a period appropriate for the anticoagulant and preservative solutions used.

Description:
The LEUKOSEP® HRC-600-C Leukocyte Reduction Filtration System for Red Blood Cells contains a leukocyte reduction filter, red cell storage container, associated tubing, clamps and connectors. The LEUKOSEP® filter is designed to effectively entrap and remove leukocytes while allowing red blood cells to pass through the media.

Performance Specifications:
The LEUKOSEP® HRC-600-C Leukocyte Reduction Filtration System for Red Blood Cells was designed and tested to meet the following FDA recommended performance criteria:

- A one-sided 95% lower confidence limit for the true proportion of units with a filtration recovery of red blood cell mass of at least 85% is greater than 95%.
- A one-sided 95% lower confidence limit for the true proportion of units with residual leukocyte content of less than 5 $x10^6$ per unit is greater than 95%.
- A one-sided 95% lower confidence limit for the true proportion of units with hemolysis at end of storage of less than 1% is greater than 95%.
- Mean 24-hour post transfusion, *in- vivo* red cell recovery at end of storage of at least 75% with standard deviation of at most 9%, and the lower limit of a one-sided 95% confidence interval for the population proportion of successes is 70% or greater. Success is defined as a subject that has at least 75% *in-vivo* 24-hour recovery.

Predicate Device:

Predicate Device		
HEMERUS LEUKOSEP® HRC-600-C Leukocyte Reduction Filtration System for Red Blood Cells	Hemerus Medical, LLC	BK070024 August 23, 2007

Biocompatibility Information:
Biocompatibility testing was performed on the HEMERUS LEUKOSEP® HRC-600-C Leukocyte Reduction Filtration System for Red Blood Cells using guidelines of ISO 10993 – *Biological Evaluation of Medical Devices* and FDA guidance document *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices May 1, 1995 (G95-1).* The LEUKOSEP® System passed all biocompatibility requirements.

Sterilization:
HEMERUS LEUKOSEP® HRC-600-C Leukocyte Reduction Filtration System for Red Blood Cells is sterilized using a validated steam sterilization process.

Bench Testing:
Device integrity testing included mechanical, functional and packaging testing. The LEUKOSEP® HRC-600-C Leukocyte Reduction Filtration System for Red Blood Cells met all design and performance requirements.

Clinical Studies:
The clinical data supporting safety and efficacy of the HEMERUS LEUKOSEP® HRC-600-C Leukocyte Reduction Filtration System for Red Blood Cells were collected from four United States investigational sites.

Table 1- LEUKOSEP® System *in-vitro* Clinical Studies

Number of Units Tested	RBC Additive Solution Added	Filter Temp	Filter Time	Mean ± SD Post Filter Red Cell Mass Recovery (%)	Mean ± SD Post Filter Residual White Cell/Unit	Mean ± SD Hemolysis at 42 Days Storage (%)
72	Within 8 Hours	Room Temp	Within 8 Hours	91% ± 2%	1.4×10^5 ± 1.6×10^5	0.4% ± 0.2%
60	Within 8 Hours	1-6 ºC	Day 1	89% ± 1%	2.6×10^5 ± 1.3×10^5	0.2% ± 0.1%
60	Up to 48 Hours	1-6 ºC	Day 3	91% ± 2%	2.2×10^5 ± 2.0×10^5	0.4% ± 0.2%

Table 2- LEUKOSEP® System *in-vivo* 24-Hour Radiolabeled Red Cell Recovery

Statistic	Result	FDA Criteria
Mean *in-vivo* Radiolabeled Red Cell Recovery (n=24) (Single Label Method)	85.2 %	≥ 75%
Standard Deviation *in-vivo* Radiolabeled Red Cell Recovery (n=24) (Single Label Method)	5.0 %	≤ 9%
Mean *in-vivo* Radiolabeled Red Cell Recovery (n=24) (Double Label Method)	85.7 %	≥ 75%
Standard Deviation *in-vivo* Radiolabeled Red Cell Recovery (n=24) (Double Label Method)	4.8 %	≤ 9%
95% Lower Confidence Limit for Population Proportion of Successes (Single Label Method)	81.7%	≥ 70%
95% Lower Confidence Limit for Population Proportion of Successes (Double Label Method)	88.3%	≥ 70%

Conclusion:
HEMERUS LEUKOSEP® HRC-600-C Leukocyte Reduction Filtration System for Red Blood Cells is substantially equivalent to the legally marketed predicate device in terms of intended use, design, scientific technology, functionality and clinical performance.

The LEUKOSEP® HRC-600-C Leukocyte Reduction Filtration System for Red Blood Cells successfully passed the FDA recommended acceptance criteria for red blood cell mass recovery, residual white cell content, hemolysis at end of storage, and 24 hour *in-vivo* radiolabeled red cell recovery.