BK030008

Premarket Notification [510(K)] Summary
(per 21 CFR 807.92)

1. **Submitted by:**

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2. **Device Name**

Trade/Proprietary Name:	Leucolab LCG2 Leukoreduction System for Red Blood Cells
Common/Usual Name:	Pre-storage Leukoreduction System for Red Blood Cells
Classification Name:	Blood Transfusion Microfilter

3. **Predicate Device:**

The Leucolab LCG2 Leukoreduction System for Red Blood Cells is substantially equivalent to other leukocyte reduction filters on the market, such as the Pall BPF4 High Efficiency Leukocyte Removal Blood Processing Filter System, marketed under BK910019 by Pall Biomedical Products Corporation.

4. **Intended use of the device**

The Leucolab LCG2 Leukoreduction System for Red Blood Cells is indicated for the leukoreduction of a single unit of red cells, at room temperature (20 to 24 C) within 8 hours of collection, or at 1 to 6 C up to 3 days after collection. The storage period for the Leukoreduced Red Blood Cells is determined by the anticoagulant or preservative solution used in their manufacture.

5. Description of the Device

The Leucolab LCG2 Leukoreduction System for Red Blood Cells consists of a pre-storage leukoreduction filter assembly, tubing and a storage container. The fluid path of the device is sterile and non-pyrogenic. The device is intended for use at a blood establishment by trained personnel. The system allows closed system processing using an FDA cleared sterile connecting device. The presence of a spike permits open system processing when the product will be used in less than 24 hours.

6. Summary of the technological characteristics of the device compared to the predicate device.

The Leucolab LCG2 Leukoreduction System for Red Blood Cells is substantially equivalent to other leukocyte reduction filters on the market. These devices have the same intended use and similar performance characteristics, and the Leucolab LCG2 System does not have any technological characteristics that raise new types of safety and effectiveness questions.

Both the Leucolab LCG2 System and the predicate device are leukocyte reduction filter systems, consisting of a pre-storage leukoreduction filter assembly, tubing, and a storage container. In both devices, the fluid path is sterile and non-pyrogenic. Both devices are designed to attach to a container of previously collected and separated Red Blood Cells (RBC) for the purpose of filtering the blood to reduce leukocytes to the FDA requirements of $\leq 5 \times 10^6$/container, while providing ≥85% RBC recovery post-filtration, and ≤1% hemolysis after storage.

7. Testing

Non-clinical and clinical testing of the Leucolab LCG2 System indicate that it meets its design requirements and provides a system for leukocyte reduction of previously collected and separated Red Blood Cells, in accordance with the current guidelines published by the FDA for these systems. Testing was also conducted to evaluate compliance with ISO 3826 and ISO 10993.

Clinical testing of the Leucolab LCG2 System demonstrated that it reduced leukocytes to a mean value of 0.249×10^6 when filtration was performed on the day of collection and 0.091×10^6 when filtration was performed on Day 3. In the same study, the predicate control device reduced leukocytes to a mean value of 0.445×10^6 when filtration was performed on the day of collection and 0.154×10^6 when filtration was performed on Day 3.

8. Conclusions

Based upon the testing and comparison to the predicate device, the Leucolab LCG2 Leukoreduction System for Red Blood Cells performs as intended and raises no new safety or effectiveness issues.