11.0 Premarket Notification [510(k)] Summary

1. Submitted by:

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2. Device Name

Trade Name: Leucolab LCG2 Leukoreduction System for Red Blood Cells

Common Name: Pre-storage Leukoreduction Filter System for Red Blood Cells

Classification Name: Blood Transfusion Microfilter

3. Predicate Device:

The Leucolab LCG2 Leukoreduction System for AS-1 Red Blood Cells was cleared for marketing (BK 030008) and its use with AS-3 Red Blood Cells is substantially equivalent. Other leukocyte reduction filters on the market are currently being used for the leukoreduction of AS-3 Red Blood Cells.

4. Intended Use of the Device

The Leucolab LCG2 Leukoreduction System for AS-1 or AS-3 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 AS-1 or AS-3 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 leukoreduced 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 has not changed significantly since it was cleared for marketing (BK 030008). It is also 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 substantially equivalent devices are leukocyte reduction filter systems, consisting of a pre-storage leukoreduction filter assembly, tubing, and a storage container. In all of these devices, the fluid path is sterile and non-pyrogenic. The devices are designed to attach to a container of previously collected and separated AS-1 or AS-3 Red Blood Cells for the purpose of filtering the blood to reduce leukocytes to the FDA requirements of $< 5 \times 10^6$/container, while providing $\geq 85\%$ RBC recovery post-filtration, and $\leq 1\%$ hemolysis after storage.

7. Testing

Non-clinical and clinical testing of the Leucolab LCG2 System with previously collected and separated Red Blood Cells (AS-3 in the present case, and AS-1 in BK 030008), meets the current FDA guidelines for leukocyte reduction filters. Testing also demonstrated compliance with ISO 3826, BF64 and ISO 10993-1.

The Leucolab LCG2 System met performance requirements for the leukoreduction of AS-3 Red Blood Cells:

- Mean residual WBC: 0.04×10^6
- Mean RBC recovery: 91.6%
- Mean Hemolysis: 0.17%

8. Conclusions

Based upon the testing and comparison to the predicate device, the Leucolab LCG2 Leukoreduction System for Red Blood Cells meets all established requirements for safe and effective leukoreduction of AS-1 or AS-3 Red Blood Cells.

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