

Special 510(k) Summary

- A) SUBMITTED BY/: NanoEnTek, Inc.
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- B) DEVICE NAME: ADAM- rWBC
- COMMON NAME: Automatic Cell Counting System
- DEVICE CLASS: 21 CFR 864.5220, Automated Differential Cell Counting System
Class II
- PRODUCT CODE: GKZ
- C) PREDICATE:
- BK120015 ADAM –rWBC Automatic Cell Counting System

D) DEVICE DESCRIPTION:

The FDA cleared ADAM-rWBC is a LED fluorescence microscope system and CCD detector encased in a portable unit. There is also microfluid chip technology and associated reagents. The system is designed for counting residual white blood cells (rWBCs) in leukoreduced blood products. The principle of the system consists of measuring stained nuclei from disrupted cells treated with lysing agent and Propidium Iodide.

The ADAM-rWBC consists of the following components:

- The ADAM-rWBC microscopic cell counting device
- ADAM-rWBC kit containing the r-Slide, r-Solution and Standard beads solution

E) INTENDED USE/INDICATIONS FOR USE:

The ADAM-rWBC system is intended for in vitro use for the enumeration of residual white blood cells (rWBCs) in leukoreduced blood products.

F) SUBSTANTIAL EQUIVALENCE COMPARISON AND DISCUSSION

This submission is for a change to the labeling in the Package Insert of the ADAM-rWBC. Currently, the package insert states not to use lipemic or hemolyzed samples. The labeling change is to allow the use of lipemic or hemolyzed samples with the ADAM-rWBC.

The following are unchanged:

- Intended Use/Indication for Use
- Method of identification
- Instrument
- Software
- Calibration
- Linear range
- Accuracy

G) PERFORMANCE TESTING

Testing was performed on lipemic (3000mg/dL of triglyceride) and hemolyzed (1500 mg/dL) samples and found to have no effect on performance.

H) OTHER - Compliance with Standards

There are no applicable performance Standards or Guidance documents associated with this device. The testing complies with CLSI

I) CONCLUSION

Laboratory testing has demonstrated that lipemic or hemolyzed samples do not affect the performance of the ADAM-rWBC. Therefore, there are no new issues of safety or effectiveness, and the device is substantially equivalent.