510(k) Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is BK030027.

Submitter Information (21 CFR 807.92(a)(1))

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Device Name/Classification (21 CFR 807.92(a)(2))

Name: BD IMAGN® Microvolume Fluorimeter and BD IMAGN rWBC Assay Kit

Classification: Class II (Regulation Code 864.5220), Automated differential cell counter

Substantially Equivalent/Predicate Device (21 CFR 807.92(a)(3))

The BD IMAGN rWBC Assay is substantially equivalent* to the BD LeucoCOUNT™ Kit for enumerating residual white blood cells (rWBCs) in leucoreduced blood cell products. LeucoCOUNT was cleared under BK970046, August 14, 1998.

* The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

The BD IMAGN rWBC Assay Kit and the LeucoCOUNT Kit have identical intended uses, measure the same sample types and have similar performance characteristics.

Device Description (21 CFR 807.92(a)(4))

The BD IMAGN rWBC Assay is intended to enumerate residual leucocytes in leucoreduced blood products. The BD IMAGN rWBC Assay system consists of:

- the BD IMAGN Microvolume Fluorimeter,
- BD IMAGN Software (with rWBC assay-specific parameters) and
- the BD IMAGN rWBC Assay Kit

The BD IMAGN microvolume fluorimeter is a tabletop optical scanning instrument that performs optical detection of up to two-color fluorescent signals and image analysis, using a helium neon laser light source emitting at 633nm. The BD IMAGN rWBC Assay Kit contains sufficient nucleic acid dye-based reagent and volumetric capillaries to perform 50 tests.

Principles of Operation of the BD IMAGN Microvolume Fluorimeter

Target cells in samples (e.g. whole blood) are labeled with fluorescent dyes or dye-labeled antibodies. An aliquot of labeled sample is drawn into a volumetric capillary. The cells are held in stasis within the capillary while being examined by a scanning 633nm Helium-Neon laser. The laser light excites fluorescence from the labeled target cells that is then detected by the optical system and stored as an electronic image of the sample within the capillary. The electronic image is analyzed using software algorithms to detect and classify cells on the basis of fluorescence intensity, size, color and shape. Target cells are counted and reported.

Intended Use (21 CFR 807.92(a)(5))

The product is a microvolume fluorimeter-based assay intended to enumerate residual leucocytes in leucoreduced blood products.

Technological Characteristics (21 CFR 807.92(a)(6))

The following summary table describes the similarities and differences between the LeucoCOUNT Kit and the BD IMAGN rWBC Assay kit.

Table 1 - Comparison of the Principal Characteristics of the BD LeucoCOUNT Kit and the BD IMAGN rWBC Assay Kit.

Characteristic or Function	***BD LeucoCOUNT Kit***	***BD IMAGN rWBC Assay Kit***
Intended Use	For in vitro diagnostic use for the enumeration of residual leucocytes in leucoreduced blood products.	Same
Specificity and Method to Identify Populations of Interest	Nucleic acid dye for leucocyte staining. Enumerate rWBCs using a flow cytometer.	Nucleic acid dye for leucocyte staining. Enumerate rWBCs using the BD IMAGN microvolume fluorimeter.
Control	Commercial or home-brew controls.	Same
Instrument	A flow cytometer equipped with 488 nm air-cooled argon ion laser for fluorescence excitation. Capable of detecting at least two-color fluorescence, forward scatter (FSC) and side scatter (SSC) and threshold on FL2.	BD IMAGN Microvolume Fluorimeter equipped with a 633nm Helium-Neon laser.
Software	Manual discrimination of rWBCs and manual calculation of results.	BD IMAGN Software with an automated software algorithm for discrimination of rWBCs and calculation of results.
Calibrations	None	None
Procedure	Manual preparation procedure.	Same
Results	Manual calculation required	rWBC counts expressed as cells/μL and cells/unit
Unstained Sample Storage	RBC Sample should be refrigerated and PA samples should be stored at room temperature.	Same for RBC. PA samples may be stored at room temperature or refrigerated (1-6°C)
Leucoreduced Sample Stability	Samples can be stained up to 48 hours post leucoreduction	Same
Stained Sample Stability	Test within 24 hours of staining	Test within 1 hour of staining

Accuracy:

Accuracy evaluations were performed at two blood banks. Accuracy was assessed separately for both red blood cell (RBC) and platelet aphaeresis (PA) products through comparative evaluation of the same sample analyzed in parallel with the BD IMAGN rWBC Assay kit and the BD LeucoCOUNT Kit. Acceptance criteria were met; the BD IMAGN rWBC Assay demonstrates acceptable accuracy relative to the predicate.

Within-Sample Reproducibility:

Within-sample reproducibility evaluations were performed at two blood banks. Reproducibility was defined as the within-sample, across-stain standard deviation. Acceptance criteria were met; the BD IMAGN rWBC Assay demonstrates acceptable precision.

Linearity:

Analysis of results from independent dilutions at concentrations spanning the assay range demonstrated that the BD IMAGN rWBC Assay is linear from 1-50 cells/μL.

Stability:

Analysis of results from multiple red blood cell and platelet apheresis product samples demonstrated that reliable residual white blood cell counts are obtained from the BD IMAGN rWBC Assay in samples up to 48 hours post leucoreduction.