

**510(k) Summary of Safety and Effectiveness**

**Applicant:** Biometric Imaging, Inc.  
1025 Terra Bella Avenue  
Mountain View, CA 94043-1829

**Contact:** Thomas P. Hartz, Jr., Ph.D.  
Vice President

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**Device Trade Name:** CEQer™ RBC Assay for use with the  
IMAGN® 2000 Microvolume Fluorimeter

**Common Name:** Automated differential cell counter

**Classification Name:** Counter, cell, differential classifier, automated

**Equivalent Device:** IMAGN® 2000 4T8® System

**Device Description:** IMAGN® 2000 Microvolume Fluorimeter is a cellular analysis platform which enables the imaging and quantitation of cells in precisely defined volumes. The CEQer assays have been developed to detect residual white blood cells in blood products.

**Intended Use** CEQer™ RBC Assay is intended for use with the IMAGN® 2000 Microvolume Fluorimeter to determine the concentration of residual white blood cells in leukocyte reduced red blood cell component.

**Comparison** CEQer™ RBC Assay when used with the IMAGN® 2000 Microvolume Fluorimeter is substantially equivalent to the IMAGN® 2000 4T8® System for imaging and quantifying specific cells in precisely define volumes.

**Nonclinical Performance Data:** None provided at this time.

**Clinical Performance Data:** Field trials at four clinical sites showed that the CEQer™ RBC Assay when used with the IMAGN® 2000 Microvolume Fluorimeter compares favorably in accuracy and sensitivity to the Nageotte chamber method and provides the advantages of automation.

**Conclusion** CEQer™ RBC Assay when used with the IMAGN® 2000 Microvolume Fluorimeter accurately and precisely determines the concentration of residual white blood cells in leukocyte reduced platelet rich plasma.