

510(k) Summary of Safety and Effectiveness

Applicant: Biometric Imaging, Inc.
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Device Trade Name: CEQer™ PRP 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™ PRP Assay is intended for use with the IMAGN® 2000 Microvolume Fluorimeter to determine the concentration of residual white blood cells in leukocyte reduced platelet rich plasma.

Comparison: CEQer™ PRP 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 three clinical sites showed that the CEQer™ PRP 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™ PRP 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.