

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

**Date Summary Prepared:** May 26, 1997

**Device Trade Name:** STELLer™ CD34 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 STELLer™ CD34 Assay has been developed to detect CD34+ cells in peripheral blood and apheresis products.

**Intended Use:** STELLer™ CD34 Assay is intended for use with the IMAGN® 2000 Microvolume Fluorimeter to determine the concentration of CD34+ cells in peripheral blood and apheresis products.

**Companion:** STELLer™ CD34 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 Data:** Biometric Imaging produced data addressing the range, precision, sensitivity of the STELLer™ CD34 Assay.

**Clinical Data:** Field trials at two clinical sites showed that the STELLer™ CD34 Assay when used with the IMAGN® 2000 Microvolume Fluorimeter compares favorably to flow cytometry and provides the advantages of automation.

**Conclusion:** STELLer™ CD34 Assay when used with the IMAGN® 2000 Microvolume Fluorimeter accurately and precisely determines the concentration of CD34+ cells in peripheral blood and apheresis products.