

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
DEVICE ONLY TEMPLATE**

**A. 510(k) Number:** #K032677

**B. Analyte(s):** **WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM (#%),**  
NEUT (#%), MXD (#%), MPV, and RDW (SD/CV)

**C. Type of Test:** Quantitative

**D. Applicant:** Sysmex America, Inc.

**E. Proprietary and Established Names:** Sysmex pocH-100i Automated Hematology  
Analyzer

**F. Regulatory Information:**

1. Regulation section(s): 864.5200 – Automated Cell Counter (Particle Counter);  
864.5220 - Automated Differential Cell Counter
2. Classification: II
3. Product Code(s): GKL; GKZ
4. Panel: Hematology (81)

**G. Intended Use:**

5. Intended use(s):  
The Sysmex pocH-100i Automated Hematology Analyzer is an automated cell counter intended for in vitro diagnostic use in a CLIA non-waived clinical laboratory (not for Point of Care use in a CLIA waived laboratory).
6. Indication(s) for use: Same
7. Special condition for use statement(s): N/A
8. Special instrument Requirements: N/A

**H. Device Description:**

The Sysmex pocH-100i Automated Hematology Analyzer is a compact instrument that provides analysis of (17) hematology parameters in whole blood mode, and the (8) bolded parameters as listed under **B. Analytes**, in pre-diluted mode.

**I. Substantial Equivalence Information:**

1. Predicate device name: Sysmex KX-21™ Automated Hematology Analyzer
2. Predicate K number(s): #K981761
3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
For use in the clinical laboratory	Sysmex pocH-100i Automated Hematology Analyzer	Sysmex KX-21™ Automated Hematology Analyzer
Detection technology	DC detection	Same
Hematology parameters	(17) parameters	Same
Reagents	Diluent, lyse solution, 3-level quality control	Same
Analysis modes	Whole blood and pre-dilute	Same
Type of unit	Compact	Same
<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Diluent and lyse reagent names	pocH-pack D; pocH-pack L	Cellpack; Stromatolyser - WH
Transducer(s)	Single	Dual

**J. Standard/Guidance Document Referenced (if applicable):**

1. NCCLS C28-A2:  
How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline, 1995
2. Guidelines for the evaluation of blood cell Analyzers including those used for differential leucocyte and reticulocyte counting and cell marker applications; ICSH 16:173, 1994
3. FDA Guidance  
Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells, 2000.

## K. Test Principle

The Sysmex pocH-100i Analyzer has a single transducer and utilizes DC detection, along with hydrodynamic focusing, for electric impedance particle counting. It employs a non-cyanide hemoglobin method that uses diluent and lysing solutions. The sample is aspirated, measured and delivered into a mixing chamber where it is diluted. The lysing reagent is then added to dissolve red cells and release the hemoglobin. The lysed sample is transferred to the transducer, where the volume and number of blood cells are determined by the DC detection method. The remaining parameters are then calculated, based upon the measured values, by a microprocessor.

## L. Performance Characteristics (if/when applicable):

### 1. Analytical performance:

#### a. *Precision/Reproducibility:*

Within-run precision studies were performed on duplicates of normal blood samples (N= 10). The %CV's ranged 0.2 – 12.5%.

Between-day precision was done on (3) levels of quality control (QC) over a 24-day period. The %CV's ranged 0.4 – 17.4%.

All results met company specifications.

#### b. *Linearity/assay reportable range:*

Serial dilutions of patient blood were tested, with expected values plotted against obtained results. Both low and high values were calculated for the (5) measured parameters: WBC, RBC, HGB, HCT, and PLT.

The R2 values ranged 0.9935 – 0.9998, which met company specifications.

#### c. *Traceability (controls, calibrators, or method):*

Testing was based upon methods traceable to the ICSH cyanmethemoglobin method; NCCLS H15-A2: Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood, 2<sup>nd</sup> Edition, Approved Standard (1994); and H7-A2: Procedure for Determining Packed Cell Volume by the Microhematocrit Method, 2<sup>nd</sup> Edition, Approved Standard (1993).

#### d. *Detection limit: N/A*

#### e. *Analytical specificity: N/A*

#### f. *Assay cut-off: N/A*

2. Comparison studies:
  - a. *Method comparison with predicate device:*

All (17) parameters were analyzed on the Sysmex pocH-100i and the Sysmex KX-21™ Automated Hematology Analyzers, using whole blood and pre-diluted samples (N=193). Linear regression equations were all within acceptable analytical limits, with “R” values ranging 0.90 – 1.00 for whole blood (except for a value, R=0.75, due to the small number of cells/types counted for one of the calculated parameters). R2 values for pre-diluted samples ranged 0.9368 – 0.9980.
  - b. *Matrix comparison: N/A*
3. Clinical studies:
  - a. *Clinical sensitivity: N/A*
  - b. *Clinical specificity: N/A*
  - c. *Other clinical supportive data (when a and b are not applicable):*

Performance data for carryover, linearity and method comparison were generated using clinical blood samples from patients with a variety of medical conditions.
4. Clinical cut-off: N/A
5. Expected values/Reference range:

Reference ranges were established for each parameter, using as a guide, NCCLS C28-A2: How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline, 1995. The company used normal donors (N=129). Females (N=67), ranged 20-79 years of age; and males (N=62), ranged 18-83 years of age. The mean age was 47 years.

## **M. Conclusion**

All data from performance studies met the established acceptance criteria for this type of device. The Sysmex pocH-100i Automated Hematology Analyzer is substantially equivalent to the Sysmex KX-21™ Automated Hematology Analyzer, a legally marketed device.