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

A. 510(k) Number:
K040073

B. Analyte:
White Blood Cell Count (WBC) and Red Blood Cell Count (RBC)

C. Type of Test:
The Body Fluid Application adds a quantitative, automated procedure for analyzing cerebrospinal fluid, serous fluid, and synovial fluid to the XE-2100 Series automated hematology analyzers, providing enumeration of the WBCs and the RBCs.

D. Applicant:
Sysmex America, Inc.

E. Proprietary and Established Names:
Body Fluid Application for the XE-2100 Series Automated Hematology Analyzer

F. Regulatory Information:

1. Regulation section:
   21 CFR 864.5220, Automated differential cell counter
2. Classification:
   Class II
3. Product Code:
   GKZ
4. Panel:
   Hematology (81)

G. Intended Use:

1. Indication(s) for use:
   The Body Fluid Application adds a quantitative, automated procedure for analyzing cerebrospinal fluid, serous fluid, and synovial fluid to the XE-2100 Series automated hematology analyzers, providing enumeration of the WBCs and the RBCs.
2. Special condition for use statement(s):
   These matrices have been validated on the XE-2100 Series: Cerebrospinal fluid, serous fluid (peritoneal, pleural, ascites, and dialysate), and synovial fluid.
3. Special instrument Requirements:
   Sysmex® Automated Hematology Analyzer, XE-2100 Series

H. Device Description:
The XE-2100 Series Body Fluid Application adds the quantitative capability of enumerating WBCs and RBCs in body fluids. The XE-Series is an automated hematology analyzer and leukocyte differential cell counter for in vitro diagnostic use in clinical laboratories.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Standard method WBC/RBC counting using a hemacytometer and microscope and Sysmex XE-2100 Series Automated Hematology Analyzer
2. Predicate K number(s):
   Sysmex XE-2100 Series (K992875)
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Same as predicate method.	To provide a quantitative determination of blood cells in cerebrospinal fluid, serous fluid, and synovial fluid.
Specimen Type	Same as predicate method.	Cerebrospinal fluid, serous fluid, and synovial fluid.
Differences		
Item	**Device**	**Predicate**
Methodology	Cell count is performed on an automated hematology analyzer	Cell count is performed manually in a counting chamber by a skilled competent technologist.
Performance	Comparison to manual count showed good correlation.	Method of cell counting using a microscope established as the predicate method.
Pro/Con	The reproducibility and accuracy of an automated method is more consistent since this method is not subject to the variation of the manual method. A large number of cells can be analyzed and several parameters rather than morphological appearance alone can be used to identify the blood cells.	The reproducibility and accuracy of the manual method will vary due to the differences in technologist skill and experience. It is a labor intensive and time consuming method.

J. Standard/Guidance Document Referenced (if applicable):
Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Cells; Final Guidance for Industry and FDA.

K. Test Principle:
The XE-2100 Series is an automated hematology analyzer previously cleared by the FDA (K992875). The XE performs hematology analyses on the WBC and RBC parameters using the following methods: RF/DC Detection Method, Sheath Flow DC

Detection Method, and Flow Cytometry Method using a Semiconductor Laser. The RF/DC detection method detects the size of blood cells by changes in direct-current resistance and the density of the blood cell interior by changes in radio-frequency resistance. Blood cells pass through the aperture of the detector surrounded by sheath fluid using the sheath flow method. The principle of flow cytometry is also used. A semiconductor laser beam is emitted to the blood cells passing through the flow cell. The forward light scattered light is received by the photodiode. The photo multiplier tube receives the lateral scattered light and lateral fluorescent light. This light is converted into electrical pulses, thus making it possible to obtain blood cell information. The combination of side scatter, forward scatter, and fluorescent intensity of nucleated cells gives and image of each cell detected in the specimen.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    - *a. Precision/Reproducibility:*
        1. Within-run precision was determined by using samples that were run in the open mode ten times consecutively. Conclusion: Results were ≤15% for WBC samples ≥0.05 x 10^3/μL and RBC samples ≥0.01 x 10^6/μL as stated in the manufacturer's specifications.
        2. Between-day precision using e-Check control material was monitored for the time period of the evaluation. Conclusion: Results were within acceptable ranges for e-Check as stated in the manufacturer's specifications.

    - *b. Linearity/assay reportable range:*
      WBC and RBC linearity were evaluated by diluting body fluid samples with instrument diluent to obtain results at low levels of detection. R squared values for WBCs ranged from 0.996 to 0.9996. R squared values for RBCs ranged from 0.9983 to 0.9998. Conclusion: The WBC and RBC parameters were linear at low levels for body fluid specimens.
    - *c. Traceability (controls, calibrators, or method):*
      N/A
    - *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:*

Table 1: Accuracy of XE vs. Manual White Blood Cell Counts

Fluid Type:	**N=**	**R**	**Slope**	**Intercept**
CSF	205	0.99	1.0	0.04
Serous*	161	0.93	1.0	0.01
Synovial	52	0.99	0.9	0.06
Body fluids combined	418	0.99	0.9	0.11

*Serous fluid included peritoneal, pleural, acites, and dyalysate samples.

Table 2: Accuracy of XE vs. Manual Red Blood Cell Counts

Fluid Type:	**N=**	**R**	**Slope**	**Intercept**
CSF	29	0.96	0.9	0.005
Serous	44	0.97	0.9	0.005
Synovial	23	0.97	0.9	0.010
Body fluids combined	96	0.97	0.9	0.006

b. *Matrix comparison*: All three body fluid types (CSF, Serous, Synovial provide strong positive linear correlations when comparison is made between the manual counts with the automated counts.

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):*
   Carryover: Data was collected by analyzing a high sample three consecutive times then analyzing a low sample three times.
   Conclusion: Carryover was ≤1% as stated in the manufacturer's specifications.
4. Clinical cut-off:
   N/A
5. Expected values/Reference range:
   Due to the unavailability of obtaining normal body fluid samples, it is difficult for laboratories to establish expected values: therefore all laboratories will reference textbook values as their expected values as was the case with these study sites.

M. Conclusion:

The Sysmex XE-2100 Series Body Fluid Application is substantially equivalent to the manual microscopic predicate method for enumeration of WBCs and RBCs in body fluids.