

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

K061616

B. Purpose for Submission:

Modification of device to add new features. The new features are: RBC correction, Graphical representation of customer-definable high/low limits on the RBC histogram, advanced bar-code reader, control folder filters, reproducibility and carryover not required as pre-calibration checks.

C. Measurand:

N/A

D. Type of Test:

The LH 780 Hematology Analyzer provides automated complete blood count, leukocyte differential, NRBC enumeration and reticulocyte analysis as well as an automated method for enumeration of RBCs and WBCs in body fluids.

E. Applicant:

Beckman Coulter

F. Proprietary and Established Names:

COULTER® LH 780 Hematology Analyzer

G. 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)

H. Intended Use:

1. Intended use(s):

The COULTER LH 780 Hematology analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for In Vitro Diagnostic Use in clinical laboratories. The COULTER LH 780 Hematology Analyzer provides automated reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs) as well as an automated method for enumeration of RBCs and WBCs in body fluids.

2. Indication(s) for use:

The purpose of the LH 780 Hematology analyzer is to separate the normal patient, with all normal system-generated parameters, from the patient who needs additional studies of any of these parameters. These studies might include further measurements of cell size and platelet distribution, manual WBC differential or any other definitive test that helps diagnose the patient's condition.

3. Special conditions for use statement(s):

N/A

4. Special instrument requirements:

N/A

I. Device Description:

The COULTER LH 780 Hematology analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for In Vitro Diagnostic Use in clinical laboratories. The COULTER LH 780 Hematology Analyzer provides automated reticulocyte analysis and enumeration of nucleated red blood cells (NRBCs) as well as an automated method for enumeration of RBCs and WBCs in body fluids.

The purpose of the LH 780 Hematology analyzer is to separate the normal patient, with all normal system-generated parameters, from the patient who needs additional studies of any of these parameters. These studies might include further measurements of cell size and platelet distribution, manual WBC differential or any other definitive test that helps

diagnose the patient's condition.

The instrument system is comprised of the analyzer and a suite of analytical reagents that allow for simultaneous quantitative determination of hemoglobin measurement, cell counting and sizing, reticulocyte determination, quality control calibration and cleaning.

J. Substantial Equivalence Information:

1. Predicate device name(s):
 - a. COULTER® LH 750 Hematology Analyzer
 - b. Sysmex™ XE-2100 Automated Hematology Analyzer
2. Predicate 510(k) number(s):
 - a. K011342, K030606 (body fluids application)
 - b. K992875
3. Comparison with predicate:

Similarities		
Item	Predicate	Device
Intended Use	See above under H. 1.	Same
Indications for Use	See above under H. 2.	Same
Method History	Coulter Principle, Hemoglobinometry, VCS technology, NRBC enumeration.	Same
Quality Controls & Calibrator	COULTER® 5C® Cell Control, COULTER® Latron™ Primer & Latron Control, COULTER® RETIC-C™ Cell Control, COULTER® LIN-C® linearity control, COULTER® S-CAL® CALIBRATOR KIT	Same

Similarities		
Item	Predicate	Device
Analysis Reagents	COULTER® LH Series Diluent, COULTER® Isoton 4 diluent, COULTER® LH Series Pak, COULTER® LH Series RETIC PAK, COULTER® Lyse S® III lytic agent, COULTER® Lyse S® 4 lytic agent.	Same
Service Diagnostics	Uses ProService Remote Diagnostics	Same
Hardware Options	Graphic/Laser Printer, LH 700 Series SlideMaker, LH 700 Series SlideStainer	Same

Differences		
Item	Predicate	Device
IVD Parameters	WBC, RBC, Hgb, MCV, MCH, MCHC, RDW, Plt, MPV, LY%, MO%, NE%, EO%, BA%, LY#, MO#, NE#, EO#, BA#, NRBC%, NRBC#, RET%, RET#, IRF, & MRV	Same plus RDW-SD
Quality Control Techniques	Daily Instruments Check, Commercial Controls, Delta Checks, Patient Controls, XM Analysis, & IQAP	Same plus Extended QC & XM Analysis
Cleaning Agent	COULTER® CLENZ	Same plus COULTER® LH Series Cleaner
Performance Specifications	Within-Run precision (CBC, Diff, Retic), Accuracy (CBC, Diff, Retic), Linearity (WBC, RBC, Hgb, & Plt), Background (WBC, RBC, Hgb, & Plt), Operating and Reportable Ranges (CBC, Diff, Retic, NRBC), Mode to Mode	Same plus Within-Run precision, Accuracy, and operating and Reportable Ranges include RDW-SD and a tighter WBC Linearity specification.

Differences		
Item	Predicate	Device
Uncorrected WBC (UWBC)	Comparison (WBC, RBC, Hgb, Plt). Result reported in a comment field.	Result reported in parameter block.
New Features Not Covered Above.	N/A	<ul style="list-style-type: none"> • RBC Correction • Graphical representation of customer-definable high/low limits on the RBC histogram • Advanced bar-code filters • Reproducibility and carryover not required as pre-calibration checks

K. Standard/Guidance Document Referenced (if applicable):

Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA

L. Test Principle:

CBC analysis is based on the established Coulter principle method of automated cell counting and spectrophotometric hemoglobin determination. The Coulter method counts and sizes cells by detecting and measuring changes in electrical resistance when a particle (such as a cell) in a conductive liquid goes through a small aperture.

Each cell suspended in a conductive liquid (diluent) acts as an insulator. As each cell goes through the aperture, it momentarily increases the resistance of the electrical path between two submerged electrodes, one located on each side of the aperture. This causes an electrical pulse that can be counted and sized. While the number of pulses indicates particle count, the size of the electrical pulse is proportional to the cell volume.

Differential and reticulocyte analysis is based on the Coulter volume, conductivity and light scatter technology (VCS). Differential analysis classification and reticulocyte analysis occur in the flow cell, where: Low-frequency current measures volume; High-frequency current senses cellular internal content through measuring changes in conductivity; Light from the laser scattered off the individual cells characterizes cellular surface, shape, and reflectivity.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision testing was performed in accordance with CLSI/NCCLS EP5-A2, *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline* and *Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA*. Acceptance criteria for each parameter were the performance specifications described in the Draft on-Line Help CD Rom, Section 13. Acceptance criteria were met.

b. *Linearity/assay reportable range:*

Linearity testing was performed in accordance with *Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cell Types; Final Guidance for Industry and FDA*. WBC, RBD, Hgb, and Plt linearity was evaluated by analyzing gravimetrically prepared dilutions of whole blood and analog preparations to cover the linear range. The values obtained were compared to the expected values for each dilution. Acceptance criteria for each parameter were the performance specifications described in the Draft on-Line Help CD Rom, Section 13. Acceptance criteria were met.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

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:*

Accuracy testing was performed in accordance with CLSI/NCCLS EP9-A, *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*. Normal and clinical samples were analyzed on the test instruments and compared against a predicate device. Non-numeric and system alarms were excluded from data analysis. Accuracy was performed for CBC, Diff, and Reticulocyte parameters, results were compared to specifications. Acceptance criteria for each parameter were the performance specifications described in the Draft on-Line Help CD Rom, Section 13. Acceptance criteria were met.

b. *Matrix comparison:*

N/A

3. Clinical studies:

a. *Clinical Sensitivity:*

There are no acceptance criteria for clinical sensitivity. Analysis of normal and clinical samples was performed for internal validation.

b. *Clinical specificity:*

There are no acceptance criteria for clinical specificity. Analysis of normal and clinical samples was performed for internal validation.

c. *Other clinical supportive data (when a. and b. are not applicable):*

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Testing was performed in accordance with CLSI/NCCLS C28-A2, *How to Define and Determine Reference Intervals in the Clinical Laboratory, Approved Guideline-Second Edition*. A normal range study was conducted to assess the Reference Ranges for the LH 780 System. Whole blood samples were collected from 126 donors (males and females) from the Beckman Coulter Inc. blood donor program. The selection of donors was consistent with guidelines stated in CLSI/NCCLS C28-A2. Reference intervals for each parameter were calculated using 95% confidence limits. Acceptance criteria were listed in the Performance Characteristics section of the Draft On-Line Help CD Rom, Section 13. Acceptance criteria were met.

N. Instrument Name:

COULTER® LH 780 Hematology Analyzer

O. System Descriptions:

1. Modes of Operation:

Open Tube and closed Tube

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No _____

3. Specimen Identification:

Barcode

4. Specimen Sampling and Handling:

Open Tube, pierced cap

5. Calibration:

COULTER® S-Cal commercial calibrators

6. Quality Control:

Daily Instruments Check, Commercial Controls, Delta Checks, Patient Controls, XM Analysis, & IQAP

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

In order to demonstrate substantial equivalence of the LH 780 Hematology Analyzer to the LH 750 hematology analyzer, the LH 750 Body fluids Application and Sysmex XE-2100 Hematology Analyzer (for RDW-SD) experiments were designed and executed based on accepted industry standards and internal product development procedures. The performance protocols for data collection adhere to CLSI/NCCLS documents, ICSH/ISLH recommended reference methods, FDA guidance documents, and scientifically valid procedures.

Data was collected internally using normal and clinical samples at the Beckman Coulter, Inc. Systems and Applications Support Laboratory in Miami, Florida. Normal whole blood

specimens were obtained from the in-house blood center using a screened pool of donors. Clinical samples were obtained by arrangement with local hospitals, using spent specimens from routine laboratory analyses. For external site testing, clinical samples were obtained by using spent specimens from routine laboratory analysis.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.