

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

A. 510(k) Number:

K032000 Abbreviated

B. Analyte:

N/A

C. Type of Test:

Quantitative

D. Applicant:

Beckman Coulter, Inc.

E. Proprietary and Established Names:

Proprietary Name: Coulter® LH 500 Hematology Analyzer

Classification Name: Automated Differential Cell Counter

F. Regulatory Information:

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

G. Intended Use:

1. Indication(s) for use:
The Coulter LH 500 is a quantitative, automated hematology analyzer for in-vitro diagnostic use in clinical laboratories. The LH 500 system provides automated complete blood count and leukocyte differential. The product also provides semi-automated reticulocyte analysis.
2. Special condition for use statement(s):
N/A
3. Special instrument Requirements:
N/A

H. Device Description

The Coulter LH 500 hematology analyzer is designed for in-vitro diagnostic use in clinical laboratories. The LH 500 provides automated complete blood count, leukocyte differential, and semi-automated reticulocyte analysis. The purpose of the LH 500 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 composed 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.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Coulter® LH 750 Hematology Analyzer
2. Predicate K number(s):
K011342
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Same as predicate	The Coulter LH 750 Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for in-vitro diagnostic use in clinical laboratories.
Analysis Reagents	Same as predicate	Coulter LH Series diluent, Pak, and lysing reagent.
Cleaning Reagent	Same as predicate	Coulter CLENZ
Hematology Quality Controls	Same as predicate	Coulter 5C Cell Control Coulter Latron Primer and Latron Control Retic-C Cell Control Lin-C Linearity Control

Differences		
Item	Device	Predicate
Reticulocyte analysis method	Semi-automated	Automated
Reticulocyte analysis reagents	Coulter ReticPrep Reagent Kit	LH Series Retic Pak
Aperture system	Single aperture	Triple aperture

J. 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

K. 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.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision testing was performed in accordance with NCCLS EP5-A, *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline*. Acceptance criteria for each parameter were the performance specifications listed on the LH 500 System Help CD Rom. 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*. Acceptance criteria for WBC, RBC, HGB, and PLT linearity were the performance criteria listed on the LH System Help CD Rom. Acceptance criteria were met.
 - 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:*
Accuracy testing was performed in accordance with NCCLS EP9-A, *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*. Acceptance criteria for each parameter were the performance specifications listed on the LH 500 System Help CD Rom. Acceptance criteria were met.
 - b. *Matrix comparison:*
N/A
3. Clinical studies:
- a. *Clinical sensitivity:*
 - b. *Clinical specificity:*
 - c. *Other clinical supportive data (when a and b are not applicable):*
There are no acceptance criteria for clinical sensitivity and specificity as no claims are made in the product labeling. Analysis of normal and clinical samples was performed for the purpose of establishing performance characteristics internally and is available in internal validation documentation.
4. Clinical cut-off:
N/A
5. Expected values/Reference range:
Testing was performed in accordance with 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 500 system. Whole blood samples were collected from 120 donors (males and females) from the Beckman Coulter Inc. blood donor program. The selection of donors was consistent with guidelines stated in NCCLS C28-A2 Reference intervals for each parameter was calculated using 95% confidence limits. Acceptance criteria were listed in the Performance Characteristics section of the LH 500 System Help CD Rom. Acceptance criteria were met.

M. Instrument Name:

Coulter LH 500 Hematology Analyzer

N. 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 or No

3. Sample Identification:
Barcode

4. Specimen Sampling and Handling:
Open tube, pierced cap

5. Assay Types:
N/A

6. Reaction Types:
N/A

7. Calibration:
Coulter S-Cal commercial calibrators

8. Quality Control:
Multiple quality control techniques using Coulter commercial control materials.

O. Other Supportive Instrument Performance Characteristics Data Not Covered In The “L. Performance Characteristics” Section Of The SE Determination Decision Summary.

In order to demonstrate substantial equivalence of the LH 500 hematology analyzer to the LH 750 hematology analyzer, experiments were designed and executed based on accepted industry standards and internal product development procedures. The performance protocols for data collection adhere to 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.

P. Conclusion:

The Beckman Coulter, Inc. LH 500 Hematology Analyzer is substantially equivalent to the Beckman Coulter, Inc. LH 750 Hematology Analyzer.