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

A. 510(k) Number:
K032342

B. Instrument Name:
Coulter® LH 750 Hematology Analyzer with Version 2B Software

C. 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. 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.

D. Other Supportive Performance Characteristics Data Not Covered In The "L. Performance Characteristics" Section Of The SE Decision Summary.

In order to demonstrate substantial equivalence of the LH 750 Hematology Analyzer with Version 2B Software to the LH 750 Hematology Analyzer with Version 2A Software (K011342), 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, 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.

E. Other Supportive Information:

The Coulter LH 750 Hematology Analyzer with Version 2B Software is designed for in vitro diagnostic use in clinical laboratories. The LH 750 provides automated complete blood count, leukocyte differential, NRBC enumeration and reticulocyte analysis. The purpose of the LH 750 Hematology Analyzer with Version 2B Software 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.

F. Conclusion:

The Coulter LH 750 Hematology Analyzer with Version 2B Software is substantially equivalent to the Coulter LH 750 Hematology Analyzer with Version 2A Software.