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

A. 510(k) Number:

K042173

B. Manufacturer and Instrument Name:

Beckman Coulter, Inc., Coulter A^{c}·T™ 5diff Cap Pierce (CP)

C. Type of Test or Tests performed:

D. System Descriptions:

1. Device Description:
   The Coulter AcT 5diff Cap Pierce is a quantitative, automated hematology analyzer and leukocyte differential analyzer capable of analyzing samples in a closed vial or open vial modes. The system consists of the Analyzer, a personal computer workstation and a printer. The AcT 5diff CP is a device manufactured for Beckman Coulter, inc. under an OEM agreement by ABX Diagnostics (ABX) of Montpellier, France. The AcT 5diff CP with version 1.29 software is currently marketed as an OEM device using the ABX Pentra C+ instrument cleared under K003677.

2. Principles of Operation:
   The CBC analysis is based on the established Coulter Principles of automated cell counting and spectrophotometric hemoglobin determination. The differential analysis uses the principles of aperture impedance, cytochemistry, focused flow impedance, and light transmission from a halogen light source. The instrument is a microprocessor driven with a PC that performs data processing and data management activities.

3. Modes of Operation:
   Open tube and Closed tube

4. Specimen Identification:
   Barcode

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

6. Calibration:
   Coulter AcT 5 diff commercial calibrators

7. Quality Control:
   Multiple quality control techniques using Coulter AcT 5diff Control Plus Reference control.

8. Software:

   FDA has reviewed the applicant's Hazard Analysis and software Documentation: Yes __X__ or No _____

E. 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

F. Intended Use:

1. Indication(s) for Use:
   The Coulter AcT 5diff Cap Pierce (CP) hematology analyzer is a 26-parameter, fully automated hematology analyzer, including a five-part leukocyte differential counter, capable of analyzing samples in a closed vial or open vial mode.

2. Special Condition for use Statement(s):
   N/A

G. Substantial Equivalence Information:

1. Predicate device name(s)and 510(k) numbers:
   a. Beckman Coulter AcT 5diff AL (k032013)
   b. Beckman Coulter HmX with AL (k922704/A1)

2. Comparison with Predicate Device:

Similarities		
Item	**Device**	**Predicate**
# of Parameters	AcT 5diff CP= 26	AcT 5diff AL= 26
Principles of Measurement	WBC= Aperture Impedance RBC= Aperture Impedance Hgb= Spectrophotometric MCV= Calculated from Hct Hct=Aperture Impedance Plt= Aperture Impedance Differential=Aperture Impedance, Light scattering Retics=N/A	Same Same Same AcT 5diff AL= Same AcT 5diff AL= Same Same Act 5diff AL= Same AcT 5diff AL= Same
Sample Volume	Open and Closed Vial Modes: CBC profile=30µL CBC/DIFF profile=53µL	AcT 5diff AL= Same
Differences		
Item	**Device**	**Predicate**
# of Parameters	AcT 5diff CP= 26	HmX with AL= 25
Principles of Measurement	MCV= Calculated from Hct Hct= Aperture Impedance Differential=Aperture Impedance, Light Scattering Retics= N/A	HmX with AL= Aperture Impedance HmX with AL= Calculated from MCV HmX with AL= Aperture Impedance, Conductivity, Laser Light Scatter (VCS) HmX with AL= Laser Light Scatter
Sample Volume	Open and Closed Vial Modes: CBC profile=30µL CBC/DIFF profile=53µL	HmX with AL: Open Vial Mode=125µL Closed Vial Mode=185µL
Throughput	Open and Closed Vial Modes: Up to 80 samples /hour	AcT 5diff AL=Open and Closed Vial Modes: Up to 60 samples/hour HmX with AL=Open and

		Closed Vial Modes: 75 samples / hour, Retics=30 samples/hour

H. 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.

I. Performance Characteristics:

1. Analytical Performance:

a. Accuracy:

Accuracy testing was performed in accordance with NCCLS EP9-A, *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*. Acceptance criteria for the WBC, RBC, Hgb, Hct, and Plt parameters will be a correlation coefficient "R" of >0.95 when assessed by duplicate analysis and compared to an automated hematology analyzer that has been calibrated and maintained to the manufacturer's recommendations. Acceptance criteria were met.

b. 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 the WBC, RBC, Hgb, Hct, and Plt parameters was listed in the Summary Report in Section 3.3 Precision—Within-Run (Reproducibility). In two verification studies, precision was verified by the analysis of n=20 replicates of a single fresh normal sample on two different AcT 5diff CP analyzers. Twenty-one replicates were analyzed, with the first replicate deleted as prime. Acceptance criteria were met.

c. Linearity:

Linearity testing was performed using a commercially available low range and full range linearity test kit. A minimum of six dilutions were used, with each dilution analyzed four times and a mean determined. The obtained mean was compared to the expected result for each dilution. Acceptance criteria for the WBC, RBC, Hgb, Hct, and Plt parameters were listed in the Summary Report in Section 3.5 Linearity. Acceptance criteria were met.

d. Carryover:

Carryover testing was performed in accordance with the ICSH guideline referenced in the FDA special control. Carryover is

assessed by analyzing a whole blood sample with high cell concentrations followed by a whole blood sample having low cell concentrations. Each sample is analyzed in triplicate. Acceptance criteria for the WBC, RBC, Hgb, and Plt parameters will be <2.0%. Acceptance criteria were met.

e. Interfering Substances:
N/A

2. Other Supportive Instrument Performance Data Not Covered Above:

a. *Specimens*: Anticoagulant
Specimen anticoagulant testing was performed in accordance with the ICSH guideline *Recommendations of the International Council for Standardization in Hematology for ethylenediaminetetraacetic acid anticoagulation of blood for blood cell counting and sizing*. The acceptance criterion was the ability of the instrument to meet product labeling using both K_3 and K_2 EDTA. Acceptance criteria were met.

J. Conclusion:

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