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

A. 510(k) Number:

K050758

B. Purpose for Submission:

New Device

C. Manufacturer and Instrument Name:

Chempaq A/S, Chempaq XBC Analyzer

D. Type of Test or Tests Performed:

Quantitative, White Blood Cells (WBC), Granulocytes (GRN), Lymphocytes (LYM), Monocytes (MON), Total Hemoglobin (Hb)

E. System Descriptions:

1. Device Description:

   The Chempaq XBC Analyzer is an automated differential cell counter. The device consists of the following components and accessories : (1) a single use cartride, called the Particle Analyzer and Qualifier (PAQ) ; and (2) a stationary Reader with a docking station, called a Cradle. The PAQ is connected to the Cradle by a simple push fit. The PAQ includes all required reagents and will, when connected to the Cradle, perform all simple manipulations required for the analysis. The sample minipulation is facilitated by electrical and pneumatic connections between the PAQ and the Cradle.

2. Principles of Operation:

   The Chempaq XBC Analyzer counts and sizes blood cells by impedance cell sizing, also known as the Coulter Sizing or Coulter Counting Principle. This concept is broadly accepted as being used in most hematology analyzers and particle counting equipment. The method is based on measurable changes in the electrical impedance produced by comparatively non-conductive particles in an electrolyte.

3. Modes of Operation:

   Random access, Point of Care

4. Specimen Identification:

   Not Available, Manual numbering

5. Specimen Sampling and Handling:

   The Chempaq XBC Analyzer analyzes a single drop (20 µL) of blood usually taken from the fingertip or a well mixed sample of venous blood already taken from the patient. Capillary blood sample from the fingertip is obtained by standard techniques and any lancing system that provides sufficient blood.

   Venous samples should be collected in containers carrying salts of EDTA as anticoagulant in a concentration of 3.7-5.4 µmol/mL of blood. The blood sample should be at room temperature and well mixed. A pipette capable of safely delivering a single drop of blood should be used to apply to the blood inlet of the PAQ.

   Heparin cannot be used as an anticoagulant.

6. Calibration:

   The Chempaq XBC Analyzer is factory calibrated when manufactured. The method of calibration is traceable to Clin. Lab. Haemat., 16(2), 131-138 (1994) for WBC and NCCLS standard H15-A3 for Hgb.

7. Quality Control:

   External controls are indicated to be necessary to meet conformance with local, state and federal regulations. An available commercial control is suggested.

8. Software:

   The Chempaq XBC Analyzer software is developed only for operating the instrument and considered to be of moderate level of concern. Algorithms for the blood cell counts and hemoglobin measurement are included in the software and validated accordingly.

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types

   Yes___X__ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 864.5220 Automated Differential Cell Counter

2. Classification:

   Class II

3 Product code:

   GKZ, Counter, Differential Cell

4. Panel:

   (81) Hematology

G. Intended Use:

1. Indication(s) for Use:

   The Chempaq XBC Analyzer is an in vitro diagnostic method intended for the quantitative determination of the concentration of white blood cells ("WBC"); granulocytes ("GRN"); lymphocytes ("LYM"); monocytes ("MON"); and total hemoglobin ("Hb") in whole blood samples (finger stick or venous sample).

   The Compaq XBC Analyzer is indicated for use in: clinical laboratories, and for point-of-care hematology determinations in doctors' offices or by healthcare professionals in hospital settings to identify and classify one or more of the formed elements of blood.

2. Special Conditions for Use Statement(s):

   Not applicable.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   Coulter® AᶜT™ Diff Analyzer, K973634

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
	Chempaq XBC Analyzer	*Coulter® A^cT™ Diff Analyzer*
Intended Use	A hematology analyzer used for the quantitative determination of the concentration of white blood cells ("WBC"); granulocytes ("GRN"); lymphocytes ("LYM"); monocytes ("MON"); and total hemoglobin ("Hb") in whole blood samples (finger stick or venous sample).	A quantitative, automated hematology analyzer used for determination of the following CBC parameters: WBC, red blood cells ("RBC"), hemoglobin ("Hb"), hematocrit ("Hct"), mean corpuscular hemoglobin ("MCH), mean corpuscular volume ("MCV"), mean corpuscular hemoglobin concentration ("MCHC), platelet count ("Plt"), LYM %/#, MON %/#, GRN %/#, RDW, and MPV.
User Population	Healthcare professionals	For use in clinical laboratories
Patient Samples	Whole blood from finger stick or venous samples.	Same
Safety Features	Built-in calibration and flagging system	Same
Reagents	Reagent system includes lytic reagent.	Reagent system includes isotonic diluent, lytic reagent, and cleaning agent.
Technological Characteristics	(1) Uses the Coulter principle for enumeration and sizing of blood cells (2) Uses an automated dilution and mixing function for sample processing. (3) Uses a built-in spectrophotometer for measurement of hemoglobin	(1) (2) (3) Same

Differences		
Item	Device	Predicate
	Chempaq XBC Analyzer	*Coulter® A^cT™ Diff Analyzer*
Major Components	(1) Single use cartridge (PAQ) (2) Stationary Reader with docking station (Cradle) (3) Display Screen for test results.	(1) Multi-use system (2) Stationary instrument with sample inlet. (3) Same
Type of Aperture for particle sizing	Single-use, disposable, polyester membrane cartridge.	Multiple-use, sapphire membrane.

I. Special Control/Guidance Document Referenced (if applicable):

Class II Special Control Guidance Document: Premarket Notification for Automated Differential Cell Counters for Immature or Abnormal Blood Cells Final Guidance for Industry and FDA, December 4, 2001

EP9-A2 *Method Comparison and Bias Estimation Using Patient Samples*, Approved Standard-Second Edition, NCCLS
EP5A *Evaluation of Precision Performance of Clinical Chemistry Device Approved Guideline*, NCCLS
EP6-A Evaluation *of the Linearity of Quantitative Measurement Procedures, Approved Guideline,* NCCLS
EP7-P *Interference Testing in Clinical Chemistry*, NCCLS
EP10 *Preliminary Evaluation of Quantitative Clinical Laboratory Method, NCCLS*
H15-A3 *Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard-Third Edition*, NCCLS
H4-A5 *Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens, Approved Standard-Fifth Edition*, NCCLS

Reference method for the enumeration of erythrocytes and leukocytes, ICSH, *Clin Lab Haematology*, 16(2): 131-138,1994.

J. Performance Characteristics*:*

1. <u>Analytical Performance</u>:

   a. Accuracy:

   Accuracy was determined using the predicate device as comparative method. Readings on the Compaq XBC were made in 3-7 replicates and readings on the predicate device were made in 3 replicates. The data was collected during 15 days using one Compaq XBC Reader and PAQs stemming from 5 different lots. The relative differences were calculated using means of both device readings. The samples were divided into 5 concentration levels of WBC, 4 concentrations levels of LYM, 2 concentrations levels of MON, 5 concentrations levels of GRN and 3 concentrations levels of HGB. The regression analysis is as follows:

Analyte	Regression	Correlation	Confidence interval slope (+/-)	Confidence interval intercept (+/-)
WBC	$y=1.006x + 0.059\ 10^9/L$ $n=130$	r=0.99	0.012	$0.094\ 10^9/L$
LYM	$y=0.911x + 0.128\ 10^9/L$	r=0.97	0.036	$0.052\ 10^9/L$

	n=130			
MON	y=0.982x + 0.090 10^9/L n=129	r=0.78	0.082	0.044 10^9/L
GRN	y=1.000x + 0.066 10^9/L n=130	r=0.99	0.016	0.070 10^9/L
Hb	y=1.011x - 0.322 10^9/L n=130	r=0.99	0.014	0.180 10^9/L

b. *Precision/Reproducibility*:

Precision was performed on three blood samples (three levels of concentration, 20 replicates) using two readers and one batch of PAQs. The results are as follows:

WBC concentration ($x10^9$/L)	Number of replicates	Within-run imprecision SD ($x10^9$/L)	Within-run imprecision CV (%)
1.84	20	0.13	7
5.43	20	0.19	3.5
16.43	20	0.74	4.5

Within-run imprecision WBC

Hb concentration (g/dL)	Number of replicates	Within-run imprecision (g/dL)	Within-run imprecision CV (%)
6.2	20	0.18	2.9
15.08	20	0.24	1.6
17.52	20	0.44	2.5

Within-run imprecision Hb

Additional precision was determined by analyzing three concentration levels of a commercial liquid blood control (using one lot) and analyzed on 20 consecutive working days. One Chempaq XBC Reader and one lot of PAQs were used. The results are as follows:

Control Blood WBC ($x10^9$/L)	N	Total imprecision SD ($x10^9$/L)	Total imprecision CV (%)
1.51	20	0.100	6.6
4.77	20	0.208	4.4
11.84	20	0.433	3.7

Control Blood LYM ($x10^9$/L)	N	Total imprecision SD ($x10^9$/L)	Total imprecision CV (%)
0.58	20	0.147	25.3
1.65	20	0.349	21.1
4.00	20	0.755	18.9

Control Blood MON ($\times 10^9$/L)	N	Total imprecision SD ($\times 10^9$/L)	Total imprecision CV (%)
0.22	20	0.041	18.6
0.67	20	0.049	7.3
1.55	20	0.076	4.9

Control Blood GRN ($\times 10^9$/L)	N	Total imprecision SD ($\times 10^9$/L)	Total imprecision CV (%)
0.70	20	0.150	21.4
2.44	20	0.305	12.5
6.28	20	0.514	8.5

Control Blood Hb (g/dL)	N	Total imprecision SD (g/dL)	Total imprecision CV (%)
6.56	20	0.217	3.3
13.13	20	0.206	1.6
18.24	20	0.319	1.7

c. *Linearity*:

A linearity study was performed using 1 venous blood sample which was divided into 2 tubes (low and high samples were prepared). A dilution scheme was outlined and resulted into 11 samples for the diluting scheme These 11 samples were randomly analyzed on 5 readers. One sample analyzed in 3 replicates. The results were as follows:

Analyte	Correlation r^2	Regression
WBC	0.99	$y=1.00x +0.0013x\ 10^9$/L
Hb	0.99	$y=1.00x +0.0048$ mmol/L

The reportable ranges are as follows:
WBC   0-100 ($\times 10^9$/L)
HB   0-21   (g/dL)

d. *Carryover*:

Not applicable.

e. *Interfering Substances*:

Interference studies were performed on EDTA, sodium citrate, triglycerides, and bilirubin. No interferences with these substances were identified.

Interference studies were performed on 6 venous blood samples containing heparin on 5 Readers. Based on the results it was concluded that there is interference of heparin and this substance cannot be used as an anticoagulant for samples used on the Chempaq XBC system.

2. Other Supportive Instrument Performance Data Not Covered Above:

K. Proposed Labeling:

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

L. Conclusion:

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