

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

A. 510(k) Number:

K032214

B. Analyte:

Ten blood cell count with three part leukocyte differential capability

C. Type of Test:

Complete blood count

D. Applicant:

Boule Medical AB, Stockholm, Sweden, represented by Clinical Diagnostic Solutions, Inc.

E. Proprietary and Established Names:

Medonic CA 620 and CA 530 Hematology Analyzers

F. 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)

G. Intended Use:

1. Indication(s) for use:
The Medonic CA 620 and CA 530 are fully automated hematology analyzers for *in vitro* diagnostic testing of whole blood specimens.
2. Special condition for use statement(s):
n/a
3. Special instrument Requirements:
n/a

H. Device Description:

The Medonic CA620/530 Hematology Analyzers are a single analyzer system, using the same electronic particle counting technology and the same software for calculating and reporting results. The CA620 and CA530 have identical parameter performance in all respects. The CA620 additionally has reporting modes, an extended calibration menu, a graphic display and an extended print format not available on the CA530. Both analyzers report all CBC parameters, but the CA530 may be configured to inhibit reporting of the WBC differential results.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Abbott CELL-DYN 1600 Analyzer (K870233) and Beckman Coulter Ac-T Diff™ (K973634).

2. Predicate K number(s):
See above
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Uses impedance method for counting and sizing of blood cells	Medonic CA620/530	Abbott CD 1600 Beckman Coulter Ac•T diff
Identical parameters		
Calculates 3 population diff plus absolute numbers		
Automatic sampling, diluting, and mixing devices		
Self cleaning sampling system		
Simultaneous analysis of RBC and WBC parameters		
Single aperture for RBC/PLT counting and sizing		
Single aperture for WBC sizing		
Coincidence correction to accommodate 2 cells entering sensing area simultaneously		
Reagent system includes a diluent, lytic reagent, and cleaner		
Uses a spectrophotometer to measure Hgb		
Stores patient, control, an calibrator results.		
Automatic calibration calculations.		

Differences		
Item	Device	Predicate
Uses volumetric metering to set aliquot size	Medonic CA620/530	Abbott CD 1600
Uses precision vacuum and count times to set aliquot size		Beckman Coulter Ac•T diff

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

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

K. Test Principle:

The Medonic CA620/530 uses the applied Coulter impedance counting principle for cellular enumeration and sizing of blood cells. The analyzer automatically aspirates an aliquot of blood specimen, prepares counting and sizing dilutions, and finally adds a lytic reagent for WBC counting and sizing and hemoglobin measurement. In addition, it uses similar reagent systems, consisting of a hematology isotonic diluent and hemolytic lyse reagent.

L. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Parameter	CV %
WBC	2.0
RBC	0.85
MCV	0.5
PLT	3.3
HGB	0.8

b. *Linearity/assay reportable range:*

Linearity +/-1%	Range
WBC	0.5-80.0
RBC	0.5-9.99
MCV	55-130
PLT	30-999
HGB	0.5-55.0
PLT Concentrate Mode (RBC<0.3 and measured on a latex solution)	30-6999

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:*

	Ac·T Diff vs CD 1600	Ac·T Diff vs CA620/530	CD 1600 vs CA620/530
Parameters			
WBC	0.99	0.99	0.99
RBC	0.98	0.99	0.98
PLT	0.95	0.94	0.92
HGB	0.99	0.99	0.98
MCV	0.98	0.99	0.97
Diff Parameters			
GRAN %	0.94	0.93	0.95
LYMPH %	0.93	0.94	0.94
MID %	0.24	0.26	0.35

b. *Matrix comparison:*

n/a

3. Clinical studies:

a. *Clinical sensitivity:*

n/a

b. *Clinical specificity:*

n/a

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:

n/a

M. Conclusion:

Boule Medical AB has shown the Medonic CA 620 and CA 530 Hematology Analyzers to be substantially equivalent to the Abbott CELL-DYN 1600 and the Beckman Coulter Ac·T Diff Hematology Analyzers

