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

A. 510(k) Number:

K071562

B. Purpose for Submission:

Original Traditional 510(k)

C. Manufacturer and Instrument Name:

DREW Scientific, Inc., D3 Hematology analyzer

D. Type of Test or Tests Performed:

16 Quantitative hematology parameters

E. System Descriptions:

1. Device Description:

   The D3 Hematology analyzer is a stand-alone benchtop, clinical laboratory instrument which analyzes in-vitro samples of whole blood to provice complete blood count and leukocyte 3-part differential count using the impedance and spectrophotometry techniques.

2. Principles of Operation:

   The impedance principle of electrical resistance is used for cell counting and sizing of WBCs, RBCs, and Plts. This is combined with optical absorbance of cyanmethemeglobin for hemoglobin. The technology combines to give a full CBC with 3-part differential in just under one minute.

3. Modes of Operation:

   Open Tube

4. Specimen Identification:

   Specimen identification is manual alphanumeric entry. A bar-code reader is an optional accessory.

5. Specimen Sampling and Handling:

   Manual sample handling using a sampling needle on the front of the instrument.

6. Calibration:

   Calibration is automatic or manual using DREW EX-CAL manufactured by R&D Systems.

7. Quality Control:

   Quality control is performed using DREW EX-TROL control materials (high, normal and low levels), manufactured by R&D Systems. The D3 stores up to 100 results per control batch for 6 different Lots. Results of each lot can be viewed as tables or through Levy-Jennings graphs.

8. Software:

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

   Yes ___X____ or No_____ Software documentation was provided at a Moderate Level of Concern.

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 DREW D3 Hematology Analyzer is a fully automated (microprocessor controlled) quantitative hematology analyzer used for the in vitro diagnostic testing of whole blood specimens.

2. Special Conditions for Use Statement(s):

   N/A

H. Substantial Equivalence Information:

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

   DATACELL 18MS PLUS (K945678)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Instrument	Hematology Analyzer, CBC + 3 part differential	Same
Measurement Principle: WBC, RBC, Plt.	Impedance	Same
Mode:	Open Tube	Same
Parameters: Leukocyte	WBC, LYM%, LYM#, MID%, MID#, GRA%, GRA#	Same
Parameters: Erythrocyte	RBC#, Hgb, Hct, MCV, MCH, MCHC, RDW	Same
Parameters:Thrombocyte	PLT, MPV	Same
Sample Type	Whole Blood	Same
Anti-coagulant	EDTA K2/ K3	Identical
Quality Controls	Manufactured by: R&D Systems (K843962) for DREW Scientific, EX-TROL	Same

Similarities		
Item	Device	Predicate
Calibrators	Manufactured by R&D Systems (K003991) for DREW Scientific, EX-CAL	Same

Differences		
Item	Device	Predicate
Measurement Principle: MCV	Volume integration	Derived from RBC cell size distribution
Measurement Principle: HCT	Volume integration	Calculation
RBC Wavelength	555nm	540nm
Specimen Sample Volume	10.0 µl (whole blood) 25.0 µl of whole blood diluted into 0.5 ml of diluent for prediluted sample mode	135.0 µl (whole blood) 65.0 µl (whole blood in samples saver mode) 25 µl of whole blood into 6.0 ml of diluent for prediluted sample mode
Patient Management	No worklist Uni-directional LIS	Worklist, Uni-directional LIS
Software Operating System	OS Epsilon embedded firmware	DOS
Memory Capacity	Last 1,000 analyses (demographics, results, & histograms)	100,000 results without histograms, 5000 results with histograms
QC Package	QC: 6 levels (100 results per level) Backup onto USB key 6 controls single level 100 results per control Levy Jennings plot Assay values can be	QC: 8 lots/3 levels (100 results per lot for each of the 3 levels) 8 controls assays (3 levels per lot) 100 results per lot (3 levels per lot) Levy Jennings Plot Assay values can be

Differences		
Item	Device	Predicate
	loaded several ways: a) manually, b) via USB key	loaded several ways: a) manually, b) via modem, c) via diskette
Display	Integrated Touch Screen	LCD Computer Screen
Computer	Integrated stand-alone computer	Built in computer
Power Requirement	90 to 265 VAC 50/60Hz	120 VAC +/- 10% 60Hz
Maximum Power Consumption	50W	300W

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

Guidance for Industry

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy: Table 1

Correlation may be evaluated with respect to DREW DATACELL 18MS+ using human blood samples, for all the measured parameters including 3 part differential.

PARAMETERS	R
WBC (K/µl)	> 0.95
LYM (%)	> 0.95
MIDS (%)	> 0.90
GRA (%)	> 0.95
RBC (M/µL)	> 0.95
HGB (g/dL)	> 0.95
HCT (%)	> 0.95
MCV (fL)	> 0.95
PLT (K/µl)	> 0.95

Accuracy: Table 2

Correlation was established by Drew Scientific using a DREW DATACELL 18MS and 124 blood samples for all the measured parameters.

	Data Range		
PARAMETERS	**Minimum**	**Maximum**	**R**
WBC (K/µl)	1.1	26.2	0.998
LYM (%)	2.3	63.1	0.989
MIDS (%)	1.4	22.2	0.956
GRA (%)	24.9	94.8	0.988
RBC (M/µL)	1.01	7.13	0.997
HGB (g/dL)	3.0	20.1	0.997
HCT (%)	8.7	62.7	0.992
MCV (fL)	61.0	115.0	0.979
RDW (%)	11.2	30.5	0.830
PLT (K/µl)	57	917	0.974
MPV (fL)	6.5	13.5	0.804

Accuracy: Table 3

An independent external laboratory obtained the following results based on 77 samples.

	Data Range		
PARAMETERS	**Minimum**	**Maximum**	**R**
WBC (K/µl)	4.3	16.8	0.996
LYM (%)	7.8	48.1	0.973
MIDS (%)	3.2	8.8	0.937
GRA (%)	44.9	88.5	0.974
RBC (M/µL)	2.76	6.24	0.983
HGB (g/dL)	9.0	16.2	0.990
HCT (%)	27.8	50.3	0.968
MCV (fL)	70.0	101.0	0.962
RDW (%)	11.0	15.7	0.757
PLT (K/µl)	91	439	0.977
MPV (fL)	6.3	13.0	0.923

b. Precision/Reproducibility: Table 4

Repeatability or simple precision was evaluated by Drew Scientific using a normal whole blood for 20 replicates. Repeatability is expressed as coefficient of variation (CV).

Parameters	Level	Mean	CV%
WBC	≥ to 6.0 × (K/µL)	7.98	2.0
LYM%	≥ to 15 %	32.23	2.9
MID%	≥ to 5 %	7.94	3.5
GRA%	≥ to 50 %	59.83	1.5
RBC	≥ to 4.0 × (M/µL)	5.168	1.0
HGB	≥ to 12.0 g/dL	15.46	0.6
HCT	≥ to 35.0 %	42.93	1.0
MCV	≥ to 80 fL	83.07	0.4
RDW	≥ to 12 %	13.24	3.3
PLT	≥ to 200× (K/µL)	307.2	3.6
MPV	≥ to 7 fL	7.72	1.2

Precision: Table 5

Two independent external laboratories using D3 analyzer obtained the following results using normal controls

Laboratory A (10 replicates - normal control)			
Parameters	**Level**	**Mean**	**CV%**
WBC	≥ to 6.0 × (K/µL)	7.59	1.4
LYM%	≥ to 15 %	25.88	1.6
MID%	≥ to 5 %	6.61	3.1
GRA%	≥ to 50 %	67.51	0.5
RBC	≥ to 4.0 × (M/µL)	4.573	1.0
HGB	≥ to 12.0 g/dL	13.63	1.0
HCT	≥ to 35.0 %	39.90	1.0
MCV	≥ to 80 fL	87.26	0.3
RDW	≥ to 12 %	14.88	2.2
PLT	≥ to 200× (K/µL)	221.6	2.7
MPV	≥ to 7 fL	7.36	2.9

Precision: Table 6 Inter-laboratory Precision

Split fresh human samples were analyzed on duplicate at two independent external laboratories within the same time frame. Inter-laboratory precision was calculated us ISO 5725-2 procedure.

Parameter		WBC	LYM %	MID%	GRA%
Mean		6.90	26.03	6.35	67.5
Est. of repeatability variance	S_r^2	0.0100	0.5625	0.0250	0.392
Est. between laboratory variance	S_L^2	0.0000	0.5000	0.0675	1.705
Estimate reproducibility variance	S_R^2	0.0100	1.0625	0.0925	2.097
	S_r	0.1000	0.7500	0.1581	0.626
	S_R	0.1000	1.0308	0.3041	1.448
	CV%	1.45%	3.96%	4.79%	2.14%
CV% claim		< 2.5%	< 5%	< 10%	< 3%

Parameter		RBC	Hgb	HCT	MCV
Mean		4.565	14.00	41.48	90.9
Est. of repeatability variance	S_r^2	0.0062	0.0050	0.4625	0.012
Est. between laboratory variance	S_L^2	0.0001	0.0025	0.0000	0.775
Estimate reproducibility variance	S_R^2	0.0063	0.0075	0.4625	0.787
	S_r	0.0791	0.0707	0.6801	0.111
	S_R	0.0795	0.0866	0.6801	0.887
	CV%	1.74%	0.62%	1.64%	0.98%
CV% claim		< 2%	< 1.5%	< 2%	< 1%

Parameter		PLT
Mean		287.8
Est. of repeatability variance	S_r^2	151.25
Est. between laboratory variance	S_L^2	0.00
Estimate reproducibility variance	S_R^2	151.25
	S_r	12.30
	S_R	12.30
	CV%	4.27%
CV% claim		< 5%

c. *Linearity*: Table 7

Linearity was established by Drew Scientific using a commercial linearity kit, each level was measured five times. In the case of MCV, latex spheres were used.

Parameters (Units)	Overall measured range
WBC (K/µL)	0.6 – 117.6
RBC (M/µL)	0.25 – 7.98
HGB (g/dL)	0.6 – 23.12
HCT (%)	2.2 – 71.0
MCV (fL)	43 - 231
PLT (K/µL)	7 - 2,806

d. *Carryover*: Table 8

Carryover was evaluated by Drew Scientific by analyzing three human samples with a high concentration, followed by (3) x runs from low (human) concentration samples. The test was repeated three times and the highest value is reported below.

	WBC	RBC	HGB	PLT
High concentration value	22.7	5.93	19.4	638
Low concentration value	3.2	2.13	6.8	85
Measured carry-over (%)	0	1.34%	0.80%	1.50%
Maximum carry-over (%)	<2.0	<2.0	<2.0	<2.0

The percentage of carry-over between samples is calculated with the following formula:

$$\text{Carry-over} = \frac{\text{(Low concentration 1) - (low concentration 3)}}{\text{(High concentration 3) – (low concentration 3)}} \times 100$$

e. Interfering Substances: Table 9 Interferences

Parameter	Specimen		Typical Findings
WBC	Nucleated RBC Cryo-globulins Platelet aggregation	(+) (+) (+)	NRBC on smear Platelet aggregates on smear
RBC	Cold Agglutinin Severe Microcytosis Fragmented RBC Leukocytes (>100.000/µL)	(-) (-) (-) (+)	↑MCV (increase), ↓HCT (decrease), red cell clumping on smear. Elevation of WBC count
HGB	Leukocytes (>100,000/µL) Lipemia Abnormal Protein	(+) (+) (+)	Elevation of Hgb ↑MCHC (increase), "milky" appearance of plasma ↑MCHC (increase), Lyses Hgb/WBC sample turn cloudy.
HCT	Cold Agglutinin Leukocytes (>100,000/µL) Abnormal Red Cell Fragility	(-) (+) (?) (?)	↑MCV (increase), ↓HCT (decrease), red cell clumping on smear. Elevation of WBC, ↑HCT
PLT	Pseudothrombocytopenia Platelet Aggregation Increased Microcytosis	(-) (-) (+) (-)	Platelet Satellitism on smear Platelet Aggregates on smear ↓MCV (decrease),

Table 5-14. Possible Interferences of Samples

(+): Instrument count is affected by an increased result.

2. Other Supportive Instrument Performance Data Not Covered Above:

   N/A

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.