510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k110381

B. Purpose for Submission:
New device

C. Manufacturer and Instrument Name:
Abbott Laboratories; CELL-DYN Emerald 22 System

D. Type of Test or Tests Performed:
Quantitative test for WBC, NEU%, NEU#, LYM%, LYM#, MON%, MON#, EOS%, EOS#, BAS%, BAS#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, and MPV parameters

E. System Descriptions:

1. Device Description:
   The CELL-DYN Emerald 22 System is a bench-top analyzer consisting of the main analyzer with data module, display station, and printer. The main analyzer, data module, and display station are housed in a single chassis. The printer is a stand-alone module.

   The CELL-DYN Emerald 22 open sampler is equipped to aspirate blood from a collection tube that has been opened and is held under the open sample aspiration probe.
2. Principles of Operation:
   The CELL-DYN Emerald 22 performs three types of measurements: Electrical Impedance, Flow Cytometry and Absorption Spectrophotometry.

   Electrical Impedance Counting is based on the measurement changes in an electrical current produced by particles (cells suspended in conductive liquid) as they pass through an aperture. The change produces a measurable electrical pulse and the number of pulses is proportional to the volume and size of the cell that produced it.

   Flow Cytometry (UNI-Flow) is based on a concept of active sample flow and passive sheath. The diluted sample is introduced into the flow cell under pressure and the sheath is utilized only to maintain the sample stream. Optical measurement of five parameters uses only light scatter.

   Absorption Spectrophotometry is the method used to measure Hemoglobin (Hb). An oxyhemoglobin chromogen is formed and measured when sample is mixed with a cyanide-free lytic reagent. An LED light source and photo detector are used to detect the chromogen. The Hb concentration is directly proportional to the light absorption of the sample. An initial blank reading is made on reagents only, and then a comparison of the blank and sample readings determines the Hb concentration of the sample.
3. Modes of Operation:
   CELL-DYN Emerald 22 only operates in an open tube mode.
4. Specimen Identification:
   Samples are identified by laboratories' sample identification procedure.

Instrument capability includes barcode, auto numbering and manual keypad entry.

5. Specimen Sampling and Handling:
   Whole blood EDTA specimens should be well mixed prior to specimen analysis. The specimen tube is aspirated by direct open tube sampling by the aspiration probe of the CELL-DYN Emerald 22 analyzer.
6. Calibration:
   Commercial calibrators and/or whole blood specimens may be used to confirm the accuracy of the CELL-DYN Emerald 22. The analyzer is calibrated at the factory. Calibration verification is performed by Abbott service personnel at installation. Calibration verification criteria should be established. The manufacturer recommends performing calibration verification when indicated by quality control, after major maintenance and service, at least every 6 months, and as directed by laboratory regulatory agencies.
7. Quality Control:
   Abbott recommends use of the commercially prepared CELL-DYN 22 Plus Controls to verify performance of the CELL-DYN Emerald 22. This tri-level control contains fixed cells and is assayed by Abbott to determine expected recovery ranges. Frequency of performing quality control runs should be determined by the customer.
8. Software:
   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:
   Hematology (81)

G. Intended Use:

1. Indication(s) for Use:
   The CELL-DYN Emerald 22 System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro diagnostic use in clinical laboratories for enumeration of the following parameters: WBC, LYM%, LYM#, MON%, MON#, NEU%, NEU#, EOS%, EOS#, BAS%, BAS#, RBC, HCT, MCV, RDW, HGB, MCH, MCHC, PLT, MPV in K_2EDTA anti-coagulated whole blood.

   The CELL-DYN Emerald 22 is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.
2. Special Conditions for Use Statement(s):
   For prescription use only.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:
   CELL-DYN 3700 System; k991605

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
	CELL-DYN Emerald 22	CELL-DYN 3700
Intended Use	The CELL-DYN Emerald 22 is a quantitative multi-parameter, automated hematology analyzer designed for in-vitro diagnostic use in clinical laboratories for the following parameters: WBC, LYM%, LYM#, MON%, MON#, NEU%, NEU#, EOS%, EOS#, BAS%, BAS#, RBC, HCT, MCV, RDW, HGB, MCH, MCHC, PLT, MPV in K_2EDTA anti-coagulated blood. The CELL-DYN Emerald 22 is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.	The CELL-DYN 3700 System is an automated, multi-parameter hematology analyzer designed for in vitro diagnostic use in clinical laboratories. Same parameters including reticulocytes.
Technology:	Electrical Impedance	Same
	LED Hgb Analysis	Same
	Optical differential	Same
Alphanumeric Spec. ID	Yes	Same
Histograms	WBC, PLT, RBC	Same
WBC Differential	5-part differential	Same

Differences		
Item	Device	Predicate
	CELL-DYN Emerald 22	CELL-DYN 3700
Device Description	Bench top analyzer	Bench top analyzer with built in loader
Instrument Size	Ht: 13.8 in. Width: 9.8 in. Depth: 13.8 in.	Ht: 24 in. Width: 30 in. Depth: 22 in.
Throughput	Approximately 45 per hr	Approximately 90 per hr
Sampling	Open Mode	Open or Closed Mode
Specimen Type	K_2EDTA anticoagulated human whole blood for all parameters	K_3EDTA anticoagulated human whole blood for all parameters
Sample size	Open Mode 28.0 µL	Open Mode 130 µL Closed Mode 240 µL
Optical Analysis	455 nm light emitting diode	5mW HeNe Laser
Patient Data Storage	1000 records	10,000 cycles
Parameter (reticulocytes)	No	Retic%, Retic ABS, IRF
Reagents	Diluent, CN-Free Lyse Reagent, CELL-DYN Easy	Diluent, CN-Free Lyse Reagent, Enzymatic

Differences		
Item	Device	Predicate
	CELL-DYN Emerald 22	CELL-DYN 3700
	Cleaner	Cleaner, Detergent, Sheath Reagent, Reticulocyte Reagent
Quality Control	6 files	20 files
Control/Calibrator	CELL-DYN 22 Plus Control and CELL-DYN 22 Plus Calibrator	CELL-DYN 26 Plus Control and CELL-DYN HemCal Plus Calibrator

I. Special Control/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

CLSI EP9-A2, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition

CLSI H20-A2, Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard-Second Edition

CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition

CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

CLSI C28-A3, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline-Third Edition

CLSI H26-P2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Proposed Standard—Second Edition

ISO 14971, Medical Devices – Application of Risk Management to Medical Devices

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:

Each parameter of the CELL-DYN Emerald 22 was compared to the predicate analyzer CELL-DYN 3700. A total of 1025 whole blood specimens were tested in duplicate on both analyzers at three clinical sites. The actual number (N) for each measurand in the correlation summary varies from total number of sample runs because the protocol required the presence of valid results for duplicate runs on both analyzers, in order to be included in the result analysis. The N represents the valid number of samples used in the analysis for each measurand. Correlation analysis was performed by regressing the first valid replicate (by site, analyzer, run date, run time) of the CELL-DYN Emerald 22 against the first valid replicate of the CELL-DYN 3700. The correlation coefficient and bias acceptance criteria were met. Bias is within the limits with no more than 5% of the observed individual bias calculations outside of

the acceptance limits. The correlation analysis and acceptance criteria are summarized in the tables below:

Correlation Analysis

Measurand	N	Range	Intercept (95% CI)	Slope (95% CI)	r (95%CI)
WBC	865	0.4-88.2	0.10 (0.06, 0.13)	0.95 (0.95, 0.96)	1.00 (1.00, 1.00)
RBC	1021	1.28-7.89	-0.05 (-0.08, -0.05)	1.00 (1.00, 1.01)	0.99 (0.99, 0.99)
HGB	1010	5.5-22.0	-0.16 (-0.20, -0.11)	1.02 (1.02, 1.02)	1.00 (0.99, 1.00)
HCT	1021	12.1-68.6	0.10 (0.10, 0.41)	1.00 (0.99, 1.00)	0.99 (0.99, 0.99)
MCV	1021	53.2-118.4	-9.57 (-11.18, -8.05)	1.12 (1.11, 1.14)	0.97 (0.97, 0.97)
MCH	1009	15.2-41.6	-2.24 (-2.84, -1.50)	1.09 (1.07, 1.11)	0.93 (0.92, 0.94)
MCHC	1009	28.5-38.1	-12.75 (-17.05, -9.70)	1.37 (1.29, 1.50)	0.47 (0.42, 0.51)
RDW	1021	12.0-35.8	1.46 (0.65, 2.14)	0.84 (0.80, 0.89)	0.79 (0.77, 0.82)
PLT	914	11-1485	4.07 (2.12, 6.08)	0.96 (0.95, 0.97)	0.99 (0.99, 0.99)
MPV	869	6.2-11.1	3.05 (2.85, 3.23)	0.63 (0.61, 0.66)	0.86 (0.84, 0.87)
NEU%	736	8.8-94.2	1.88 (1.42, 2.32)	0.97 (0.97, 0.98)	1.00 (1.00, 1.00)
LYM%	714	2.0-86.8	0.30 (0.22, 0.53)	1.00 (0.99, 1.01)	0.99 (0.99, 0.99)
MON%	714	0.8-34.9	0.42 (0.21, 0.63)	0.96 (0.94, 0.99)	0.91 (0.90, 0.92)
EOS%	736	0.0-20.1	0.22 (0.19, 0.25)	0.93 (0.91, 0.94)	0.97 (0.96, 0.97)
BAS%	739	0.0-5.5	0.04 (-0.16, 0.24)	0.26 (0.03, 0.49)	0.63 (0.59, 0.67)
NEU#	736	0.2-19.3	0.06 (0.03, 0.08)	0.95 (0.95, 0.96)	1.00 (1.00, 1.00)
LYM#	714	0.0-29.9	0.05 (0.03, 0.06)	0.95 (0.93, 0.96)	0.99 (0.99, 1.00)
MON#	714	0.0-3.7	-0.00 (-0.01, 0.01)	0.99 (0.96, 1.01)	0.96 (0.95, 0.96)
EOS#	736	0.0-2.0	0.02 (0.01, 0.02)	0.86 (0.83, 0.89)	0.97 (0.96, 0.97)
BAS#	739	0.0-0.1	-0.00 (-0.00,- 0.00)	0.06 (0.0, 0.11)	0.12 (0.05, 0.19)

Correlation Coefficient and Bias Acceptance Criteria

Measurand	Target Range	r-value	Bias
WBC	0.1-100	≥ 0.95	< 2.0 K/µL (± 0.2) ≥ 2.0 K/µL (± 10%)
RBC	1.0-7.0	≥ 0.95	< 3.0 M/µL (± 0.2) ≥ 3.0 M/µL (± 6%)
HGB	3-22	≥ 0.95	< 7 g/dL (± 1.0) ≥ 7 g/dL (± 0.5)
HCT	15-60	≥ 0.95	< 30% (± 3) ≥ 30% (± 6%)
MCV	55-120	≥ 0.95	± 5
RDW	open	≥ 0.75	n/a
PLT	1-1500	≥ 0.95	n/a
PLT	0-150	≥ 0.95	< 10 K/µL (± 4) ≥ 10 to 50 K/µL (± 25%) ≥ 50 K/µL (± 20%)
MPV	open	≥ 0.75	n/a
LYM%	open	≥ 0.75	> 45% (± 5)
NEU	open	≥ 0.75	> 76% (± 5)
MON	open	≥ 0.75	> 10% (± 5)
EOS	open	≥ 0.75	< 8% (± 2) ≥ 8% (-1 to 2)
BAS	open	n/a	> 2% (-1 to 2)

Comparison with manual microscopy as the reference method was completed for WBC percent differential populations. The mean of two WBC percent differential microscopy readings on each specimen was compared with the average CELL-DYN Emerald 22 results. A total of 226 samples were used for the correlation study and is summarized in the table below:

Measurand	Min	Max	Intercept (95% CI)	Slope (95% CI)	r (95% CI)
NEU%	5.1	94.4	1.48 (-0.32, 3.40)	0.96 (0.93. 0.98)	0.97 (0.96, 0.98)
LYM%	1.0	91.8	1.29 (0.58, 1.92)	0.93 (0.90, 0.96)	0.97 (0.97, 0.98)
MON%	1.4	39.8	1.03 (0.46, 1.42)	1.03 (0.94, 1.12)	0.88 (0.84, 0.90)
EOS%	0.0	20.1	0.22 (0.14, 0.30)	1.08 (1.01, 1.16)	0.94 (0.92, 0.95)
BAS%	0.0	1.9	0.26 (0.22, 0.30)	0.08 (0.01, 0.158)	0.12 (-0.01, 0.25)

The ability of the CELL DYN Emerald 22 to flag abnormal samples was evaluated per CLSI H20-A2 in comparison with the reference method (Manual Microscopy). A total of 284 samples were included in the WBC combined morphological and distributional flagging statistical analysis and is summarized in the table below:

		Microscopy		
		Positive	Negative (Normal)	Total
Cell -Dyn Emerald 22	Positive	160	29	189
	Negative (Normal)	16	79	95
	Total	176	108	284

Overall Agreement = (79 + 160) / 284 x 100% = 84.2%
Specificity = 79 / (79 + 29) x 100% = 73.2%
Sensitivity = 160 (16 + 160) x 100% = 90.9%

b. Precision/Reproducibility:

The following tables represent the results of imprecision (reproducibility) specifications for the CBC and WBC differential parameters using normal fresh blood. The studies were performed at two sites. The stated CV% in the table represents instrument imprecision from 16 runs and 20 replicates per run. Precision for the WBC differential parameters is represented by standard deviation (SD).

CELL-DYN Emerald 22 Operator's Manual Performance Specifications			**ACCEPTANCE CRITERIA**	
Measurand	**Mean Range Tested**	**Observed %CV Range**	**First tier Observed %CV (OPS Manual)**	**Second tier Requirements[a]**
WBC	4.8-10.2	0.8-2.3	2.5%	15%
RBC	4.27-5.63	0.7-1.4	2%	6%
HGB	13.0-15.4	0.2-0.9	1.5%	7%
HCT	37.5-45.2	0.8-1.5	2%	6%
MCV	75.9-93.7	0.3-0.6	1%	N/A
RDW	13.1-17.2	1.3-2.7	4%	N/A
PLT	186-337	2.2-5.2	5%	25%
MPV	6.9-10.3	1.0-2.8	3%	N/A

CELL-DYN Emerald 22 Operator's Manual Performance Specifications				**ACCEPTANCE CRITERIA**	
Measurand	**Mean Range Tested**	**Minimum SD Observed**	**Maximum SD Observed**	**Observed % CV (OPS Manual) / SD**	**Second tier Requirements[a]**
NEU%	44.3-74.1	0.53	1.37	4%	Emerald Mean ± 3*1.00**
LYM%	13.3-43.4	0.44	1.35	5%	Emerald Mean ± 3*1.01**
MON%	6.2-13.5	0.36	1.00	10%	Emerald Mean ± 3*0.62**
EOS%	0.7-6.3	0.21	0.60	10%	Emerald Mean ± 3*0.31**
BAS%	0.2-0.3	0.06	0.14	40% / 0.15	Emerald Mean ± 3*0.15**

[a]Second tier requirements are maximum values allowed.
**SD is taken from the maximum observed pooled within-run estimate from the verification studies.

The following table represents repeatability, within-device imprecision and reproducibility using commercial controls. Two runs per day with 2 replicates per run per level were completed for 20 days, on three CELL-DYN Emerald 22 instruments at two study sites. The overall variability includes within-run, between-run, between-day and between instrument variance components.

Measurand	Control Level	Mean	Within-run		Between-run		Between-day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
WBC	Low	2.4	0.08	3.3	0.05	2.2	0.06	2.6	0.11	4.7
	Normal	7.2	0.15	2.1	0.15	2.1	0.21	2.9	0.30	4.2
	High	19.1	0.47	2.5	0.25	1.3	0.51	2.7	0.74	3.9
RBC	Low	2.19	0.026	1.2	0.016	0.7	0.022	1.0	0.037	1.7
	Normal	4.51	0.048	1.1	0.031	0.7	0.031	0.7	0.065	1.4
	High	4.93	0.051	1.0	0.036	0.7	0.048	1.0	0.079	1.6
HGB	Low	5.9	0.05	0.8	0.08	1.4	0.00	0.0	0.09	1.6
	Normal	13.5	0.08	0.6	0.05	0.4	0.06	0.5	0.11	0.8
	High	17.1	0.11	0.7	0.05	0.3	0.07	0.4	0.14	0.8
HCT	Low	15.6	0.19	1.2	0.12	0.8	0.14	0.9	0.27	1.7
	Normal	34.5	0.36	1.0	0.17	0.5	0.27	0.8	0.48	1.4
	High	43.1	0.44	1.0	0.29	0.7	0.39	0.9	0.65	1.5
MCV	Low	71.3	0.34	0.5	0.23	0.3	0.10	0.1	0.42	0.6
	Normal	76.5	0.19	0.2	0.27	0.4	0.00	0.0	0.33	0.4
	High	87.3	0.26	0.3	0.24	0.3	0.19	0.2	0.40	0.5
MCH	Low	27.1	0.33	1.2	0.34	1.3	0.10	0.4	0.48	1.8
	Normal	30.0	0.29	1.0	0.14	0.5	0.16	0.5	0.36	1.2
	High	34.7	0.29	0.8	0.23	0.7	0.25	0.7	0.45	1.3
MCHC	Low	38.0	0.47	1.2	0.58	1.5	0.00	0.0	0.75	2.0
	Normal	39.2	0.37	0.9	0.17	0.4	0.20	0.5	0.45	1.2
	High	39.8	0.33	0.8	0.27	0.7	0.24	0.6	0.49	1.2
RDW	Low	14.6	0.32	2.2	0.17	1.1	0.00	0.0	0.36	2.5
	Normal	15.8	0.32	2.0	0.17	1.1	0.00	0.0	0.37	2.3
	High	14.0	0.26	1.9	0.10	0.7	0.07	0.5	0.29	2.0
PLT	Low	43	5.7	13.4	1.7	3.9	0.3	0.8	6.0	14.0
	Normal	250	7.9	3.2	6.1	2.4	6.5	2.6	11.9	4.8
	High	494	12.7	2.6	13.0	2.6	16.3	3.3	24.4	4.9
MPV	Low	9.7	0.55	5.7	0.13	1.3	0.00	0.0	0.56	5.8
	Normal	9.4	0.19	2.0	0.09	0.9	0.03	0.3	0.21	2.2
	High	9.3	0.12	1.3	0.09	1.0	0.07	0.8	0.17	1.8
NEU%	Low	36.2	1.03	2.8	0.45	1.2	0.11	0.3	1.13	3.1
	Normal	52.7	0.71	1.3	0.00	0.0	0.37	0.7	0.80	1.5
	High	76.0	0.59	0.8	0.00	0.0	0.04	0.1	0.59	0.8
LYM%	Low	50.0	1.07	2.1	0.51	1.0	0.37	0.7	1.24	2.5
	Normal	35.5	0.72	2.0	0.20	0.6	0.55	1.5	0.93	2.6
	High	14.8	0.41	2.8	0.18	1.2	0.18	1.2	0.48	3.3
MON%	Low	10.8	0.57	5.2	0.31	2.8	0.17	1.6	0.67	6.2
	Normal	8.2	0.43	5.2	0.22	2.7	0.05	0.7	0.48	5.9
	High	4.5	0.25	5.6	0.11	2.4	0.08	1.7	0.29	6.3
EOS%	Low	2.8	0.47	16.7	0.00	0.0	0.10	3.4	0.48	17.1
	Normal	3.5	0.30	8.4	0.11	3.1	0.15	4.4	0.35	10.0
	High	4.5	0.27	6.1	0.11	2.4	0.15	3.2	0.33	7.3

Measurand	Control Level	Mean	Within-run		Between-run		Between-day		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
BAS%	Low	0.1	0.08	77.9	0.00	0.0	0.01	9.0	0.08	78.4
	Normal	0.2	0.07	37.4	0.04	22.3	0.03	17.3	0.09	46.8
	High	0.2	0.06	32.5	0.02	12.1	0.01	7.0	0.07	35.3
NEU#	Low	0.9	0.05	5.9	0.03	3.1	0.02	2.7	0.06	7.2
	Normal	3.8	0.10	2.6	0.09	2.4	0.13	3.6	0.19	5.0
	High	14.5	0.36	2.5	0.24	1.6	0.39	2.7	0.59	4.0
LYM#	Low	1.2	0.06	4.8	0.02	1.6	0.02	1.7	0.06	5.3
	Normal	2.5	0.09	3.4	0.00	0.0	0.05	2.1	0.10	4.0
	High	2.8	0.12	4.2	0.00	0.0	0.06	2.1	0.13	4.7
MON#	Low	0.3	0.04	15.6	0.02	8.1	0.01	4.0	0.05	18.0
	Normal	0.6	0.04	7.3	0.02	3.5	0.01	2.4	0.05	8.4
	High	0.9	0.06	6.8	0.02	2.0	0.03	3.1	0.07	7.7
EOS#	Low	0.1	0.03	27.7	0.00	0.0	0.00	2.7	0.03	27.8
	Normal	0.2	0.03	13.9	0.03	10.5	0.02	7.3	0.05	18.9
	High	0.9	0.06	7.2	0.01	1.7	0.04	5.2	0.08	9.0
BAS#	Low	0.0	0.00	NA	0.00	NA	0.00	NA	0.00	NA
	Normal	0.0	0.00	NA	0.00	NA	0.00	NA	0.00	NA
	High	0.0	0.03	NA	0.01	NA	0.00	NA	0.03	NA

c. Linearity:

The analytical measurement range (AMR) was established by using fresh whole blood and commercial kits. Fresh blood specimens (1025 samples) were run in duplicate and pooled correlation data were analyzed using Passing-Bablok regression over the whole data set. Linearity for MCV and the upper limit for HCT were derived from fresh blood correlation analysis.

Measurand	Units*	AMR
WBC	K/µL	0.4 - 90
RBC	M/µL	1.20 - 8.30
HGB	g/dL	5.5 - 22.0
HCT	%	12.1 - 66.1
MCV	fL	53.2 - 118.4
PLT	K/µL	11 - 1485

*Results are expressed in Standard (US) units

d. Carryover:

Carryover was determined by running whole blood specimens with high target values (HTV) of WBC, RBC, HGB, and PLT. Each specimen was run in triplicate followed by three aspirations of whole blood specimens with low target values (LTV). Carryover % was calculated by using the following equation: % Carryover = (LTV1-LTV3)/ (HTV3-LTV3) x 100. Results were within specifications (≤1%) for WBC, RBC and HGB and (≤2%) for PLT.

Measurand	Low Target	High Target	% Carryover
WBC	>0 and <3	>90	<1%
RBC	>0 and <1.5	>6.20	<1%
HGB	>0 and <5.0	>22.0	<1%
PLT	>0 and <100	>900	<2%

e. Interfering Substances:

Studies for interference were evaluated for bilirubin, lipemia and hemolysis. Statistical analysis of the data was based on CLSI EP7-A2.

Interference due to bilirubin was evaluated in 40 samples spiked with a low bilirubin control reagent for WBC, RBC, HGB, HCT and PLT, and 34 samples for WBC differentials. The estimated bilirubin concentration was 7.26 mg/dL for each sample. Bilirubin interference was observed for LYM% and PLT measurements; however, a review of data indicated that the interference effect was caused by the artifacts from the sample manipulation procedure. No other measurands were impacted by bilirubin.

Lipid interference was evaluated in 40 samples added with Intralipid for WBC and differentials, and 44 samples for RBC, HCT, and PLT. The estimated lipid concentration was 600 mg/dL for each sample. The data demonstrated that lipid interferes with the HGB determination at 600mg/dL. No other measurands were impacted by lipid at this concentration.

Interference due to hemolysis was evaluated in 34 samples for RBC, HGB, HCT and PLT, 32 samples for WBC, and 32 samples for WBC differentials. The interference of hemolysis was observed for HCT; however, a review of data indicated that the interference effect was caused by the artifacts from the sample manipulation procedure. No other measurands were impacted by hemolysis.

f. Background Counts:

Daily Start-up background counts were performed on CELL-DYN Emerald 22 and were verified by each site against the specifications. Start-up background specifications were achieved before data collection. The CELL-DYN Emerald 22 background specifications are as follows:

Background Specifications:

Measurand	Background Concentration Limits*
WBC	≤ 0.5 K/µL
RBC	≤ 0.1 M/µL
HGB	≤ 0.2 g/dL
PLT	≤ 10.0 K/µL
DIF**	≤ 100 cells

* Results are expressed in Standard (US) units except for DIF

** DIF number of cells counted on scattergram

2. <u>Other Supportive Instrument Performance Data Not Covered Above:</u>

a. Stability Studies:

The Performance with Aged Blood (PAB) test procedure was used to evaluate the performance of the CELL-DYN analyzers with blood stored at refrigerated (RF) and room temperatures (RT) as it ages over a specified time period. The mean of duplicate runs was utilized to calculate the difference from the 1-hour analysis point to all other scheduled analysis points for each specimen. In order to obtain the % difference, the results were divided by the mean of the 1-hour time point. The study was performed on a total of ten (10) donor

subjects with two sets of five (5) subjects. The study demonstrated data was within ±5.4% for room temperature storage up to 24 hours and up to ±10% for refrigerated temperature storage up to 12 hours to support the claim.

b. Reference Intervals:
A total of 135 samples from males and females were collected to establish the overall reference range. The manufacturer recommends each laboratory establish its own reference range.

Measurand	Number	95% Range	
		Lower	Upper
WBC K/µL	135	3.4	8.8
NEU%	135	41.8	79.7
LYM%	135	11.5	44.1
MON%	135	4.8	11.6
EOS%	135	0.3	7.5
BAS%	135	0.1	0.6
NEU#	135	1.7	6.4
LYM#	135	0.5	2.7
MON#	135	0.3	0.8
EOS#	135	0.0	0.4
BAS#	135	0.0	0.1
RBC M/µL	135	4.02	5.49
HGB g/dL	135	12.7	16.3
HCT %	135	36.4	46.8
MCH pg	135	27.1	34.0
MCHC g/dL	135	33.5	36.2
MCV f/L	135	79.1	96.3
RDW %	135	12.9	17.8
PLT K/µL	135	157	393
MPV fL	135	7.0	10.0

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.