510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

K072869

B. Purpose for Submission:

Traditional 510(k) with modifications of a previously cleared device.

C. Measurand:

The device enumerates white blood cell populations, certain T-lymphocyte subsets, and hemoglobin concentration from human whole blood.

D. Type of Test:

Quantitative, automated flow cytometry.

E. Applicant:

PointCare Technologies, Inc.

F. Proprietary and Established Names:

PointCare *NOW* System

G. Regulatory Information:

1. Regulation section:

   21 CFR 864.5220

2. Classification:

   Class II

3. Product code:

   GKZ

4. Panel:

   Hematology (81)

H. Intended Use:

1. Intended use(s):

   The PointCare *NOW* System is an automated hematology system intended for in vitro diagnostic use in performing the direct enumeration of major white blood cell populations, certain t-lymphocyte subset, and hemoglobin concentration from human whole blood.

2. Indication(s) for use:

   Whole blood samples can be analyzed with the PointCare *NOW* System for the following parameters: White Blood Cell count, Lymphocyte Count, Lymphocyte %, CD-4 Lymphocyte Count, CD-4 Lymphocyte %, Monocyte Count, Monocyte %, Neutrophil Count, Neutrophil %, Eosinophil Count, Eosinophil %, Hemoglobin Concentration.

3. Special conditions for use statement(s):

   N/A

4. Special instrument requirements:

   N/A

I. Device Description:

The PointCare Now System uses an integrated touch screen interface and a processor as its central processing unit for system operation and data analysis. The epsilon OSE-based software analyses the patient sample for immune hematology parameters, with automated cluster finding algorithms. The Internal Storage Memory allows for the storage of up to 8,000 analyses. The included memory stick/travel drive facilitates the easy transfer of patient results from the system computer to another, and additionally expands the system to store up to 50,000 analyses.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   a. FlowCare/AuRICA Flow Cytometer

   b. Sysmex XE-2100 Hematology Analyzer

c. FlowCare PLG System for EPICS XL Flow Cytometry Systems

2. Predicate 510(k) number(s):

   a. K041882

   b. K992875

   c. K043215

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Specimen Sample	Anticoagulated whole blood	FlowCare/AURICA: Same Sysmex XE-2100: Same
CD4 Reagent	Anti-CD4 monoclonal antibody conjugated to colloidal gold substrate	FlowCare/AURICA: Same
Principle of Operation	Light Scatter and Impedance	Sysmex XE-2100: Same

Differences		
Item	Device	Predicate
Intended Use	Determination of WBC count, 4-part differential, CD4 T-Lymphocyte count, CD4 %, and hemoglobin.	FlowCare AuRICA: WBC count, Lymphocyte count, Lymphocyte %, CD4 T-Lymphocyte count, and CD4 %. Sysmex XE-2100: 5-part differential, hemoglobin, plus other hematologic parameters including RBCs and platelets. FlowCare PLG: CD4 % (CD4 T-Lymphocyte count=CD4% x Lymphocyte count from hematology analyzer.

Differences		
Item	Device	Predicate
Specimen Sample	Anticoagulated whole blood	FlowCare PLG: Lysed anticoagulated whole blood.
CD4 Reagent	Anti-CD4 monoclonal antibody conjugated to colloidal gold substrate.	FlowCare PLG: Anti-CD4 monoclonal antibody labeled with fluorochrome.
Instrumentation:	Compact flow-based immune hematology analyzer with integrated touch screen and software.	FlowCare AuRICA: Compact flow-based immune hematology analyzer with computer and software. Sysmex XE-2100: Standard hematology analyzer with computer and software. FlowCare PLG: Standard flow cytometer with computer and software.
Principle of Operation	Light scatter and impedance	FlowCare AuRICA: Light scatter FlowCare PLG: Light scatter and fluorescence

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

a. 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 Staff, January 11, 2002.

b. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 29, 1998.

L. Test Principle:

The system uses a photometer for Hgb, and impedance orifice for WBC, and a multi-angle light scatter cytometer for all other parameters. The multi-angle light scatter cytometer measures wide angle light scatter as a cell granularity index and low angle scatter as a cell size index. The gold particle anti-CD4 monoclonal antibody conjugate binds to the cell

surface and imparts granularity to the cell. Wide angle light scatter is used to detect granular cells and forward angle scatter is used to size cells making it possible to distinguish and enumerate CD4 positive T-Helper lymphocytes from other lymphocytes and other white blood cell types.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The precision study was performed to assess the within-run precision and total precision of the PointCare NOW system by replicate measurements of control materials. Control materials were analyzed on two PointCare Now instruments in accordance with the instructions for use. For each instrument, the precision study was performed on three days. On each day, testing consisted of three separate runs. In each run, three replicate measurements were performed for each level of control material. The control materials used were Bi-level Hematology Controls (Streck STak-CHEX Low and Normal.

Table 1: Summary of Within-Run Precision and Total Precision

		PointCare NOW S/N 0015							
Level		WBC#	NEUT#	NEUT%	MONO#	MONO%	EOS#	EOS%	HGB
Low N = 27	*Grand Mean*	2.7	1.1	41.9	0.3	10.1	0.1	2.9	6.2
	Within-Run Precision:								
	Std. Dev.	0.1	0.1	1.6	0.0	1.5	0.0	0.7	0.1
	CV(%)	2.5	4.8	3.9	14.9	14.9	21.2	22.7	0.8
	Total Precision:								
	Std. Dev.	0.1	0.1	2.4	0.0	1.5	0.0	0.7	0.1
	CV(%)	2.7	5.5	5.8	15.3	14.9	21.2	22.7	1.2
Normal N = 27	*Grand Mean*	7.6	3.9	50.9	0.7	9.4	0.7	5.7	9.8
	Within-Run Precision:								
	Std. Dev.	0.1	0.1	1.6	0.1	1.3	0.1	0.7	0.0
	CV(%)	1.2	3.7	3.1	14.0	13.9	14.0	11.9	0.4
	Total Precision:								
	Std. Dev.	0.1	0.1	1.7	0.1	1.3	0.1	0.8	0.0
	CV(%)	1.3	3.7	3.4	14.0	13.9	14.0	14.6	1.2

		PointCare NOW S/N 0019							
Level		WBC#	NEUT#	NEUT%	MONO#	MONO%	EOS#	EOS%	HGB
Low N = 27	*Grand Mean*	2.6	1.2	44.5	0.2	9.4	0.1	2.8	6.1
	Within-Run Precision:								
	Std. Dev.	0.1	0.1	1.6	0.1	2.5	0.0	0.5	0.1
	CV(%)	3.8	6.0	3.6	30.5	26.5	4.8	18.5	1.1
	Total Precision:								
	Std. Dev.	0.1	0.1	2.1	0.1	2.5	0.0	0.5	0.1
	CV(%)	3.8	7.4	4.7	30.5	26.5	4.8	19.0	1.5
Normal N = 27	*Grand Mean*	7.4	3.9	53.2	0.7	9.2	0.4	5.8	9.6
	Within-Run Precision:								
	Std. Dev.	0.1	0.1	1.4	0.1	1.5	0.0	0.3	0.1
	CV(%)	1.0	2.7	2.5	15.2	16.2	9.3	4.7	0.6
	Total Precision:								
	Std. Dev.	0.1	0.1	1.4	0.1	1.5	0.0	0.3	0.1
	CV(%)	1.3	3.0	2.6	15.8	16.3	9.3	4.7	1.1

A precision study was performed to assess the within-day precision of the PointCare NOW System by replicate measurements of whole blood samples. Whole blood samples were analyzed on two PointCare NOW instruments in accordance with the instructions for use. For each instrument, the precision study was performed on one day and testing consisted of ten separate runs. Four whole blood samples were used and selected to fall within three ranges (3,000-6,000 cells/µL; 6,000-8,000 cells/µL; and 8,000-10,000 cells/µL). The results demonstrated acceptable performance for the PointCare NOW System.

b. Linearity/assay reportable range:

A linearity study was performed to assess the performance of the PointCare NOW System over a wide range of cell concentrations. For each parameter, measurements were made for cell concentration levels spanning the respective method ranges (full range). Also, WBC count and hemoglobin were also evaluated in the low range. For both the full range and low range studies, six concentration levels were analyzed. Samples for the full range study were prepared using a concentrated whole blood sample diluted with autologous platelet poor plasma to achieve the desired concentration levels. The sample for each concentration level was analyzed four times in random sequence on each of the two PointCare NOW instruments.

Table 2: Summary of Linearity Study

Analysis of Results	WBC Count	Mono Count	Neut Count	Eos Count	HGB
Test for Linearity:					
N	24	24	24	24	24
Linear Fit:					
Correlation (r)	0.999	0.996	0.999	0.996	0.999
linear slope	0.995	0.992	0.997	0.946	1.000
linear intercept	0.307	-0.014	0.067	0.079	0.134
Quadratic Fit: ax^2+bx+c					
quad fit a	-0.0010	0.1066	0.0079	0.0916	-0.0066
quad fit b	1.0363	0.7560	0.8261	0.8224	1.1218
quad fit c	0.1976	0.0183	0.0742	0.0864	-0.0183
Standard Error	1.7668	0.1298	1.2104	0.1250	0.3800
t value	**0.0005**	**0.8211**	**0.0066**	**0.7326**	**0.0173**
critical t value	*2.0796*	*2.0796*	*2.0796*	*2.0796*	*2.0796*
Inference	**linear**	**linear**	**linear**	**linear**	**linear**

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

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:

A multi-site (in-house and two outside sites) prospective study was conducted to evaluate the performance of the PointCare NOW System and reagents. A total of 249 whole blood samples met the study criteria and were analyzed by both the PointCare NOW method and two outside sites with cleared predicate devices.

Table 3: Method Comparison with Predicate Devices

		WBC	LYM	LYM%	NEU	NEU%	MON	MON%	EOS	EOS%	CD4DP	CD4SP	CD4%	HGB
		Ladymeade Barbados												
Comparison	Pearson (r)	0.986	0.967	0.983	0.991	0.982	0.834	0.711	0.990	0.965	0.876	0.869	0.824	0.965
	slope	0.933	1.011	0.909	0.864	0.925	0.783	0.684	0.961	0.907	0.793	0.752	0.798	0.783
	intercept	0.293	-0.056	2.943	0.280	2.925	0.093	2.441	0.100	2.246	40	48	2.453	2.571
	n	98	98	100	98	100	98	100	98	100	94	94	96	100
PointCare NOW	mean value	5.9	2.2	39.1	2.9	47.3	0.5	8.0	0.3	5.7		414	19.5	12.5
	min value	1.1	0.4	12.0	0.2	10.9	0.1	1.5	0.1	1.4		40	2.9	4.1
	max value	24.3	7.1	81.7	17.4	81.0	1.6	16.3	5.8	64.8		1265	50.9	18.0
Reference Method	mean value	6.1	2.3	39.9	3.1	47.6	0.5	8.1	0.2	4.0	540	537	22.7	12.6
	min value	1.1	0.5	11.2	0.2	11.2	0.1	3.1	0.0	0.0	2	3	0.3	3.0
	max value	26.7	5.0	69.3	20.4	79.6	2.1	16.2	5.8	66.4	1934	1740	69.5	16.8
		PointCare Technologies												
Comparison	Pearson (r)	0.996	0.997	0.991	0.993	0.982	0.980	0.836	0.875	0.834	0.992	0.989	0.556	0.976
	slope	1.095	1.055	1.003	1.093	0.969	1.139	0.890	1.020	1.165	0.903	0.934	0.903	0.917
	intercept	-0.403	-0.052	-0.352	-0.325	0.134	0.007	1.706	0.112	1.281	111	123	3.725	1.222
	n	88	88	88	88	88	88	88	88	88	67	67	67	88
PointCare NOW	mean value	9.0	3.1	32.5	4.6	54.4	0.9	9.1	0.3	4.1		1488	47.6	13.6
	min value	2.9	0.7	14.7	1.1	15.6	0.2	4.7	0.1	0.6		139	8.8	7.0
	max value	37.2	22.2	68.2	16.1	74.1	5.9	20.3	1.0	8.7		11699	77.2	17.6
Reference Method	mean value	8.6	3.0	32.8	4.5	56.0	0.8	8.3	0.2	2.4	1493	1427	48.9	13.4
	min value	3.0	0.7	15.0	1.2	15.7	0.2	4.5	0.0	0.4	58	50	7.5	6.9
	max value	35.0	21.5	68.0	15.0	74.4	5.1	20.0	0.9	5.8	12943	12023	70.7	22.0
		Belmont Medical												
Comparison	Pearson (r)	0.985	0.969	0.991	0.990	0.983	0.773	0.761	0.927	0.955				0.994
	slope	0.953	1.008	1.008	0.896	0.932	0.977	0.778	0.609	0.700				1.002
	intercept	0.157	0.146	2.595	0.186	1.532	0.039	2.164	0.079	0.923				0.699
	n	61	61	61	61	61	61	61	61	61				61
PointCare NOW	min value	3.7	1.0	11.7	1.1	30.0	0.3	6.1	0.1	0.6				9.6
	max value	18.4	4.0	55.5	14.4	79.8	1.2	16.1	0.8	11.8				18.5
	mean value	7.2	2.0	28.8	4.4	59.8	0.6	8.3	0.2	3.1				14.7
Reference Method	min value	3.8	0.8	8.8	1.2	32.2	0.3	3.7	0.0	0.1				8.9
	max value	18.7	3.6	52.5	16.0	85.5	1.0	13.0	1.1	15.9				17.5
	mean value	7.4	1.8	26.0	4.7	62.5	0.6	7.9	0.2	3.1				14.0
		Pooled - All Sites												
Comparison	Pearson (r)	0.991	0.994	0.983	0.985	0.984	0.966	0.770	0.969	0.940	0.989	0.986	0.883	0.956
	slope	1.059	1.049	0.913	0.966	0.924	1.124	0.801	0.939	0.904	0.916	0.950	0.952	0.908
	intercept	-0.374	-0.051	3.285	0.041	2.638	-0.031	1.955	0.088	1.648	28	13	0.057	1.365
	n	247	247	249	247	249	247	249	247	249	161	161	163	249
PointCare NOW	min value	1.1	0.4	12.0	0.2	10.9	0.1	1.5	0.1	0.6		40	2.9	4.1
	max value	37.2	22.2	81.7	17.4	81.0	5.9	20.3	5.8	64.8		11699	77.2	20.1
	mean value	7.2	2.6	36.2	3.7	50.4	0.6	8.5	0.3	5.0		873	31.1	12.9
Reference Method	min value	1.1	0.5	8.8	0.2	11.2	0.1	3.1	0.0	0.0	2	3	0.3	3.0
	max value	35.0	21.5	69.3	20.4	85.5	5.1	20.0	5.8	66.4	12943	12023	70.7	22.0
	mean value	7.3	2.4	34.0	4.0	54.2	0.6	8.1	0.2	3.2	967	911	33.8	13.2

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical Sensitivity:

N/A

b. Clinical specificity:

The antigen specificity of the CD4 monoclonal antibody has been previously established by the Fourth and Fifth International Workshops for Leukocyte Typing.

c. Other clinical supportive data (when a. and b. are not applicable):

A carryover study was performed to assess the effect of a whole blood sample on the background counts in subsequent analyses. The study was performed on two PointCare NOW instruments for the three different detection methods (WBC #, Hgb and Cytometer).

Table 4: Carryover

Level	Replicate	PointCare NOW S/N 0019		
		WBC#	HGB	CYT
High	*1*	19.5	16.5	26532
	2	19.9	16.5	31237
	3	19.6	16.3	29228
Low	*1*	0.1	0.0	148
	2	0.1	0.0	88
	3	0.0	0.0	48
	Percent Carryover	**0.51%**	**0.00%**	**0.34%**
Level	**Replicate**	**PointCare NOW S/N 0015**		
		WBC#	**HGB**	**CYT**
High	*1*	20.8	17.4	32248
	2	20.7	17.4	33279
	3	20.1	17.4	34223
Low	*1*	0.1	0.0	169
	2	0.0	0.0	34
	3	0.0	0.0	20
	Percent Carryover	**0.50%**	**0.00%**	**0.44%**

4. Clinical cut-off**:**

   N/A

5. Expected values/Reference range:

   Expected values for each parameter for the PointCare NOW were calculated using an assumed health Northeaster United States population.

   Table 5: Expected Values/Reference Range

PointCare NOW Parameter	Males				Females				Combined (Males + Females + Unknowns)			
	N	Range		Mean ± SD	N	Range		Mean ± SD	N	Range		Mean ± SD
		Min	Max			Min	Max			Min	Max	
WBC	39	4.7	9.8	6.7 ± 1.4	45	3.7	11.4	7.2 ± 1.9	134	3.7	13.3	7.0 ± 2.0
HGB	39	11.9	17.3	15.2 ± 1.2	45	11.7	15.6	13.9 ± 0.9	134	11.2	17.1	14.2 ± 1.3
LYM	39	1.1	3.0	1.9 ± 0.5	45	1.1	3.4	2.1 ± 0.6	134	1.1	4.0	2.0 ± 0.6
LYM%	39	14.3	41.2	28.3 ± 6.5	45	13.2	44.4	30.6 ± 6.9	134	14.3	45.8	29.9 ± 7.2
NEU	39	2.5	6.7	4.0 ± 1.1	45	1.5	7.1	4.2 ± 1.4	134	1.9	8.0	4.1 ± 1.3
NEU%	39	45.9	68.5	59.4 ± 6.4	45	44.4	78.0	58.2 ± 7.0	134	41.5	74.1	57.9 ± 7.2
MON	39	0.4	0.9	0.6 ± 0.2	45	0.3	0.9	0.6 ± 0.2	134	0.3	1.3	0.6 ± 0.2
MON%	39	6.1	12.9	8.7 ± 1.6	45	6.1	11.3	7.9 ± 1.4	134	5.6	12.9	8.3 ± 1.6
EOS	39	0.1	0.4	0.2 ± 0.1	45	0.1	0.7	0.2 ± 0.1	134	0.1	0.7	0.3 ± 0.1
EOS%	39	1.0	7.1	3.2 ± 1.4	45	0.9	7.0	3.4 ± 1.5	134	1.0	7.8	3.7 ± 1.6
CD4	9	443	1029	739 ± 230	10	725	1686	1070 ± 291	56	369	1718	941 ± 330
CD4%	9	25.3	46	37.8 ± 6.6	10	40.7	58.5	51.8 ± 6.7	56	21.1	74.0	48.7 ± 12.4

N. Instrument Name:

PointCare *NOW* System

O. System Descriptions:

1. Modes of Operation:

   Fully-automated cap piercing, closed tube system with position recognition.

2. Software:

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

   Yes ____X____ or No _____ Software was reviewed at a Moderate Level of Concern.

3. Specimen Identification:

   Barcode reader with tube position verification.

4. Specimen Sampling and Handling:

   Fully-automated closed tube piercing, automated mixing, and control reaction temperature.

5. Calibration:

   The PointCare NOW System is factory calibrated.

6. Quality Control:

   PointCare recommends running fixed whole blood hematology controls, CBC*NOW* Control Normal and CBC*NOW* Control Low, and fixed whole blood CD4 controls, CD4*NOW* Control Normal and CD4*NOW* Control Low, at the beginning of each work day before performing sample analysis.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

N/A

Q. Proposed Labeling:

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

R. Conclusion:

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

S. Other Supportive Device and Instrument Information:

N/A