510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k102644

B. Purpose for Submission:
Replacement of the Analytical Module (AM) CPU board utilized in the ADVIA 2120/2120i Hematology Analyzers

C. Manufacturer and Instrument Name:
Siemens Healthcare Diagnostics Inc.; ADVIA® 2120 Hematology Auto analyzer and 2120i Hematology Auto analyzer with Auto slide

D. Type of Test or Tests Performed:
Quantitative test for WBC, RBC, Hgb, CN-Free Hgb, Calculated Hgb, MCV, Hct, MCH, MCHC, CHCM, RDW, HDW, Plt, MPV, Neut (%/#), Lymph (%/#), Mono (%/#), Eos (%/#), Baso (%/#), LUC (%/#), NRBC (%/#), Reticulocyte [Retic (%/#), MCVg, MCVr, CHCMg, CHCMr, CHg, CHr], CSF [WBC, RBC, Neut (%/#), Lymph (%/#), Mono (%/#), MN (%/#), PMN (%/#)], and Body Fluid [TNC, RBC] parameters.

E. System Descriptions:

1. Device Description:
   The ADVIA 2120/210i Hematology Systems with Auto Slide are an integrated option of hematology analyzers with complete blood cell count, leukocyte differential cell count, reticulocyte analysis capability, nucleated red blood cell count, quantitative determination of blood cells in Cerebrospinal Fluid (CSF), enumeration of the total nucleated cell (TNC) count and RBC count for pleural, peritoneal, and peritoneal dialysis (PD) specimens and a slide stainer designed to provide reflexive slide making/staining without user intervention based upon pre-selected, user-definable criteria.

   The ADVIA 2120/210i Hematology systems with Auto slide consists of the following: an analytical module that aspirates, dilutes, and analyzes whole blood samples; an auto sampler that automatically mixes, identifies, and presents the samples for processing; a computer workstation that controls the instrument, provides primary user interface with the instrument and manages the data produced by the instrument; a printer that optionally generates reports based on the instrument results and an auto slide module that prepares a wedge smear from a drop of blood, places it on a microscope slide and stains the slide in accordance with Wright, Wright-Giemsa and May-Grunwald Giemsa Staining techniques.
2. Principles of Operation:
   Refer to individual 510(k) clearances below:
   k930148 (H*3 Reticulocyte measurands: Retic, MCVg, MCVr, CHCMg, CHCMr, CHg, CHr)
   k954954 (Reticulocyte measurands: Retic, MCVg, MCVr, CHCMg, CHCMr, CHg, CHr)
   k971998 (ADVIA 120 measurands except NRBC, body fluids and CSF)
   k003796 (ADVIA 120 CSF measurands: CSF WBC, Neut, Lymph, Mono, MN, PMN)

k012904 (ADVIA 120 CN-free Hgb measurand)
k022668 (ADVIA 120 Calculated Hgb measurand)
k022331 (ADVIA 120 revised measurands: CSF WBC, Neut, Lymph, Mono MN, PMN)
k042251 (ADVIA 2120 measurands except NRBC and body fluids)
k051693 (ADVIA 2120 with Auto slide, NRBC, all measurands except body fluids)
k090346 (ADVIA 2120/2120i Body fluids Application measurands: RBC, TNC)

3. Modes of Operation:
   Refer to individual 510(k) clearances in item 2 above.
4. Specimen Identification:
   Refer to individual 510(k) clearances in item 2 above.
5. Specimen Sampling and Handling:
   Refer to individual 510(k) clearances in item 2 above.
6. Calibration:
   Refer to individual 510(k) clearances in item 2 above.
7. Quality Control:
   Refer to individual 510(k) clearances in item 2 above.
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 ADVIA 2120 and ADVIA 2120i with autoslide are quantitative, automated hematology analyzers that provide:
   - A complete blood count (CBC) consisting of WBC, RBC, Hgb, CN-Free Hgb, Calculated Hgb, MCV, Hct, MCH, MCHC, CHCM, RDW, HDW, CH, Plt, MPV.
   - A leukocyte differential count consisting of Neut (%/#), Lymph (%/#), Mono (%/#), Eos (%/#), Baso (%/#), LUC (%/#).
   - A reticulocyte analysis consisting of Retic (%/#), MCVg, MCVr, CHCMg, CHCMr, CHg, CHr.
   - A nucleated red blood cell count consisting of NRBC (%/#).
   - Enumeration of the total nucleated cell (TNC) count and RBC count for pleural, peritoneal, and peritoneal dialysis (PD) specimens.

   Note: Above measurands are determined (in whole blood, pleural, peritoneal,

or peritoneal dialysis specimens with K2 and/or K3 EDTA anti-coagulants).

- Quantitative determination of blood cells in Cerebrospinal Fluid (CSF) consisting of WBC, RBC, Neut (%/#), Lymph (%/#), Mono (%/#), MN (%/#), PMN (%/#).

In addition, the system provides the added capability to automatically prepare and stain high quality blood smears on a microscope slide.

2. Special Conditions for Use Statement(s):
   For prescription use only.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:
   ADVIA 2120 Hematology Auto analyzer with current CPU board; k042251
2. Comparison with Predicate Device:

Similarities		
Item	**ADVIA 2120 and 2120i with current 386ex CPU**	**ADVIA 2120/2120i with ARM9 CPU**
Parameters	CBC Results: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, CHCM, RDW, HDW, CH, PLT Differential Results: NEUT, LYMPH, MONO, EOS, BASO, LUC, NRBC (% and absolute) Platelet Results: PLT, MPV Reticulocyte Results: %RETIC, #RETIC, MCVr, CHCMr, CHr, MCVg, MCVr, CHCMg, CHg CSF Results: CSF RBC, CSF WBC, CSF MN, CSF PMN, CSF NEUT, CSF LYMPH, CSF MONO BF Results: TNC, RBC	Same
Morphology Results	WBC: Left Shift, Atypical Lymph, Blasts, Immature Granulocytes, Myeloperoxidase Deficiency RBC and PLT: NRBC, ANISO, MICRO, MACRO, HC VAR, HYPO, HYPER, RBC Fragments, RBC Ghosts, Platelet Clumps, Large Platelets	Same
User Interface personal computer	• Intel based processor • Windows 2000 • Floppy drive • Network card • Modem	Same
User Interface external peripherals	• Keyboard • Mouse • Hand-held barcode scanner • Printer	Same

Similarities		
Item	**ADVIA 2120 and 2120i with current 386ex CPU**	**ADVIA 2120/2120i with ARM9 CPU**
Electrical Power	Voltage selectable for single-phase: 100 Vac (6 Amps) - 240 Vac (3 Amps) Frequency: 50/60Hz	Same
Temperature	Operating: 18°C to 32°C Storage:-29°C to 60°C	Same
Relative Humidity	Operating: 15%-80% (noncondensing)	Same
Sample Mode Volumes	Automatic Closed-Tube: 175µL Manual Closed-Tube: 175µL Manual Open-Tube: 175µL	Same
Test Selectivity/ Throughput	CBC 120 samples/hr CBC/Diff 120 samples/hr CBC/Diff/Retic 74 samples/hr CBC/Retic 74 samples/hr Retic 74 samples/hr With Autoslide slide making enabled: CBC 108 samples/hr CBC/Diff 108 samples/hr	Same
Sample Capacity	150 samples 15 racks of 10 tubes	Same
Barcode reader	Reads up to 14 digits Automatic label code discrimination Compatible barcode types: 1. Codabar 2. Interleaved 2 of 5 3. Code 39 4. Code 128 5. EAN and JAN (8 and 13)	Same
Data Management	• TDC version 9 or higher • Database storage capacity of 10,000 records, including graphics • Review and edit capability o User-defined windows o User-defined reports o User-defined ranges based on age and sex for Normal, Rerun, Panic, and Delta Check criteria • Bi-directional and host query communication protocols • Quality control o 3D bar graph o Levey-Jennings plot o SDI graph o Table format • Remote QC • ILQC programs • Patient moving average • User assistance o Context sensitive help o Operator's guide o Procedure wizards o Problem solving diagnostics o Remote diagnostics	Same

Similarities		
Item	**ADVIA 2120 and 2120i with current 386ex CPU**	**ADVIA 2120/2120i with ARM9 CPU**
Reagents	• CBC TIMEPAC o Baso o HGB o RBC/PLT o Defoamer • CN-Free CBC TIMEPAC o Baso o CN-Free HGB o RBC/PLT o Defoamer • DIFF TIMEPAC o Perox 1 o Perox 2 o Perox 3 o Perox Sheath • autoRetic • EZ KLEEN • Sheath/Rinse • CSF	Same
Calibrators	• ADVIA OPTIpoint • ADVIA SETpoint	Same
Controls	• ADVIA TESTpoint Low • ADVIA TESTpoint Normal • ADVIA TESTpoint High • ADVIA TESTpoint Retic Low • ADVIA TESTpoint Retic High • ADVIA TESTpoint 3-in-1 Abnormal1 • ADVIA TESTpoint 3-in-1 Normal • ADVIA TESTpoint 3-in-1 Abnormal2	Same

Differences		
Item	**ADVIA 2120 and 2120i with current 386ex CPU**	**ADVIA 2120/2120i with ARM9 CPU**
Real-time Control	Intel 386ex CPU running Nucleus OS	ARM9 CPU running Nucleus OS
User Interface software	ADVIA 2120/2120i user interface software (v5.8)	ADVIA 2120/2120i user interface software (v6.0)
Communication Interface	BNC Ethernet cable (10Base-2)	RJ-45 Ethernet Cable (100Base-TX)

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

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

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

CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Proposed Standard-Second Edition

J. Performance Characteristics:

1. Analytical Performance:

a. Accuracy:

Testing was performed in three hardware/software configurations as follows:

Configuration 1	Configuration 2	Configuration 3
System software V5.8	System software V6.0	System software V6.0
386ex CPU board (P/N: 067-1452-01)		ARM 9 CPU board, Cycle 2 (P/N: 067-B794-01)
CPU Cover/Shield (P/N: 067-1448-01)		CPU Cover/Shield (P/N: 067-1627-01)
BNC Cable (P/N: 067-B391-02)		RJ45 Ethernet Cable (P/N: 664-1516-01)

Configuration 1 is the current hardware/software configuration. Configuration 2 is the current hardware configuration, but uses a software version that can support both hardware configurations. Configuration 3 has both the new hardware and new software configuration.

Testing was performed on 219 whole blood samples, 20 body fluid samples, 80 NRBC samples, and 52 CSF samples. All samples were assayed on an ADVIA 2120i in all three configurations. Samples were run duplicate, but only the first replicate was used for the analysis. The results of the regression analysis comparing all three configurations show equivalence in analytical performance, meeting bias specifications set by the sponsor.

Configuration 1 versus Configuration 2

CBC/Diff Parameter	**r**	**Slope**	**Intercept**	**Syx**	**Average X**	**Average Y**	**Observed Bias**	**Bias Specs**
WBC	0.999	1.03	-0.27	0.5	11.45	11.54	0.09	±0.15
RBC	0.998	1.00	0.01	0.05	3.28	3.29	0.01	±0.05
Hgb	0.997	0.98	0.1	0.1	9.2	9.2	0.0	±0.1
MCV	0.998	0.99	0.9	0.6	91.1	91.0	-0.1	±1.0
CHCM	0.995	0.99	0.4	0.2	32.8	32.9	0.1	±0.5
RDW	0.999	1.00	0.0	0.1	16.9	16.9	0.0	±1.0
HDW	0.999	0.99	0.04	0.03	3.23	3.25	0.02	±0.2
Plt	0.998	0.98	3	14	236	234	-2	±6
MPV	0.890	0.84	1.8	0.8	10.5	10.7	0.2	±0.5
%Neut	0.995	0.99	0.8	2.5	61.4	61.3	-0.1	±0.5
%Lymph	0.991	0.98	0.7	2.6	22.1	22.3	0.2	±0.5
%Mono	0.989	0.98	0.1	1.1	8.0	7.9	-0.1	±1.5
%Eos	0.944	0.99	0.1	0.7	1.9	1.9	0.0	±0.2
%Baso	0.969	1.00	0.0	0.4	0.7	0.7	0.0	±0.2
%LUC	0.985	0.98	0.0	1.7	6.2	6.0	-0.2	±0.5
%Retic	0.992	0.99	0.02	0.31	2.2	2.2	0.0	±0.5
CHr	0.989	0.98	0.4	0.6	32.7	32.5	-0.2	±0.5
%NRBC	0.819	0.75	1.1	2.0	5.2	5.0	-0.2	±0.5
Body Fluid Parameter	**r**	**Slope**	**Intercept**	**Syx**	**Average X**	**Average Y**	**Observed Bias**	**Bias Specs**
TNC	0.998	1.03	-2.7	25.4	299	304	5	±10
RBC	0.99997	1.01	0.1	0.8	29	29	0	±10
CSF Parameter	**r**	**Slope**	**Intercept**	**Syx**	**Average X**	**Average Y**	**Observed Bias**	**Bias Specs**

CBC/Diff Parameter	r	Slope	Intercept	Syx	Average X	Average Y	Observed Bias	Bias Specs
WBC	0.995	1.06	-9	33	245	251	6	±15
RBC	0.999	1.01	-3	23	355	357	2	±15
%MN	0.992	1.00	0.6	2.3	52	53	1	n/a
%PMN	0.992	1.00	-0.7	2.3	48	47	-1	n/a
%Neut	0.992	1.00	-0.6	2.2	47	47	0	n/a
%Lymph	0.988	1.06	-1.3	2.5	38	39	1	n/a
%Mono	0.826	0.71	4.0	1.9	14	14	0	n/a

Configuration 1 versus Configuration 3

CBC/Diff Parameter	r	Slope	Intercept	Syx	Average X	Average Y	Observed Bias	Bias Specs
WBC	0.999	1.03	-0.24	0.6	11.45	11.56	0.11	±0.15
RBC	0.998	1.00	-0.01	0.04	3.28	3.27	-0.01	±0.05
Hgb	0.996	0.99	0.0	0.2	9.2	9.2	0.0	±0.1
MCV	0.996	0.99	0.7	0.8	91.1	90.9	-0.2	±1.0
CHCM	0.994	0.98	0.7	0.2	32.8	32.9	0.1	±0.5
RDW	0.999	1.00	0.0	0.2	16.9	16.9	0.0	±1.0
HDW	0.998	1.00	0.01	0.04	3.23	3.26	0.03	±0.2
Plt	0.997	0.99	0	18	234	234	0	±6
MPV	0.906	0.83	2.0	0.7	10.5	10.8	0.3	±0.5
%Neut	0.996	0.99	0.6	2.3	61.4	61.5	0.1	±0.5
%Lymph	0.991	1.00	0.1	2.7	22.1	22.2	0.1	±0.5
%Mono	0.987	0.98	0.0	1.2	8.0	7.8	-0.2	±1.5
%Eos	0.962	0.97	0.0	0.6	1.9	1.8	-0.1	±0.2
%Baso	0.966	0.98	0.0	0.4	0.7	0.7	0.0	±0.2
%LUC	0.986	0.97	0.2	1.6	6.2	6.1	-0.1	±0.5
%Retic	0.991	1.02	0.03	0.34	2.21	2.28	0.1	±0.5
CHr	0.992	0.98	0.4	0.5	32.7	32.6	-0.1	±0.5
%NRBC	0.814	0.78	1.0	2.1	5.2	5.0	-0.2	±0.5
Body Fluid Parameter	**r**	**Slope**	**Intercept**	**Syx**	**Average X**	**Average Y**	**Observed Bias**	**Bias Specs**
TNC	0.996	1.03	-16	34	299	292	-7	±10
RBC	0.9998	1.00	0.0	2.0	29	29	0	±10
CSF Parameter	**r**	**Slope**	**Intercept**	**Syx**	**Average X**	**Average Y**	**Observed Bias**	**Bias Specs**
WBC	0.996	1.02	-4	29	245	246	1	±15
RBC	0.999	0.99	3	17	355	354	-1	±15
%MN	0.993	1.01	0.3	2.2	52	53	1	n/a
%PMN	0.993	1.01	-0.8	2.2	48	47	-1	n/a
%Neut	0.993	1.01	-1.0	2.1	47	47	0	n/a
%Lymph	0.988	0.99	0.9	2.4	38	39	1	n/a
%Mono	0.878	0.85	2.0	1.8	14	14	0	n/a

b. Precision/Reproducibility:

Whole blood samples, simulated body fluid and CSF samples were assayed in 20 consecutive replicates on an ADVIA 2120i in configurations 2 and 3 to verify that the two test configurations meet the within run precision specifications. The observed results pass the precision specifications if either the SD or the CV% specification is met.

Whole Blood Precision

		Configuration 2			Configuration 3			Specifications	
Parameter	**n**	**Mean**	**SD**	**% CV**	**Mean**	**SD**	**% CV**	**SD**	**% CV**
WBC	20	4.32	0.1	2.36	4.36	0.1	2.24	0.2	2.66
RBC	20	4.35	0.03	0.7	5.04	0.02	0.4	0.06	1.2
Hgb	20	12.8	0.10	0.76	15.1	0.09	0.58	0.14	0.93
MCV	20	90.1	0.2	0.19	88.9	0.2	0.25	0.7	0.78
CHCM	20	33.5	0.04	0.1	34.7	0.06	0.2	0.25	0.8
RDW	20	13.0	0.07	0.52	13.3	0.06	0.43	0.25	1.92
HDW	20	2.52	0.012	0.46	2.50	0.009	0.38	0.1	3.57
Plt	20	325	8.0	2.45	205	6.0	2.91	8.8	2.93
%Neut	20	53.3	0.7	1.29	68.0	0.5	0.69	1.4	2.15
%Lymph	20	26.9	0.9	3.2	15.1	0.6	4.1	1.1	4.4
%Mono	20	8.5	0.6	6.6	9.9	0.5	5.1	0.9	15
%Eos	20	7.6	0.4	5.4	5.0	0.4	7.5	0.5	25
%Baso	20	0.8	0.1	16.2	0.7	0.1	10.2	0.5	50
%LUC	20	2.9	0.3	10.8	1.2	0.2	17.2	0.5	25
%Retic	20	1.2	0.1	7.1	0.9	0.1	6.2	0.4	20

Body Fluid Precision

Autosampler									
		Configuration 2			Configuration 3			Specifications	
Parameter	**n**	**Mean**	**SD**	**% CV**	**Mean**	**SD**	**% CV**	**SD**	**% CV**
TNC	20	521	22.4	4.3	523	25.6	4.9	n/a	≤15
RBC	20	53	1.8	3.4	52	2.0	3.7	n/a	≤10

Manual Closed Tube Sampler									
		Configuration 2			Configuration 3			Specifications	
Parameter	**n**	**Mean**	**SD**	**% CV**	**Mean**	**SD**	**% CV**	**SD**	**% CV**
TNC	20	517	18.8	3.6	516	22.2	4.3	n/a	≤15
RBC	20	52	1.6	3.0	53	1.8	3.3	n/a	≤10

Manual Open Tube Sampler									
		Configuration 2			Configuration 3			Specifications	
Parameter	**n**	**Mean**	**SD**	**% CV**	**Mean**	**SD**	**% CV**	**SD**	**% CV**
TNC	20	505	23.5	4.7	460	33.9	7.4	n/a	≤15
RBC	20	54	2.0	3.8	50	1.6	3.1	n/a	≤10

CSF Precision

		Configuration 2			Configuration 3			Specifications	
Parameter	**n**	**Mean**	**SD**	**% CV**	**Mean**	**SD**	**% CV**	**SD**	**% CV**
WBC	20	88	3.8	4.3	100	3.3	3.3	≤15	≤15
RBC	20	111	6.5	5.9	102	4.5	4.4	≤15	≤15
%MN	20	93	5.1	5.5	94	4.2	4.5	≤20	≤20
%PMN	20	91	4.4	4.8	105	5.9	5.6	≤20	≤20

c. Linearity:

Linearity was tested using commercially prepared linearity controls. Each level of the control was assayed 4 times in configurations 2 and 3. Linearity was tested in whole blood, body fluid, and CSF modes. The table below summarizes linearity results. Over the ranges tested, none of the results exceeded the maximum deviation specified.

Parameter	Analytical Range	Configuration 2 Range tested	Configuration 2 Range tested	Specifications
WBC (10^3cells/µL)	0.02 – 400	0.00 – 448.60	0.00 – 405.52	Maximum deviation: ±0.5 x 10^3cells/µL or 5.0% (whichever is greater)
RBC (10^6cells/µL)	0.0 – 7.0	0.00 – 7.67	0.00 – 7.67	Maximum deviation: ±0.1 x 10^6 cells/µL
Hgb (g/dL)	0.0 – 22.5	0.0 – 25.0	0.0 – 24.5	Maximum deviation: ±0.2g/dL or ±2.0% (whichever is greater)
PLT (10^3cells/µL)	5 – 3500	0 – 5196	0 – 3675	Maximum deviation: ±5 or ±5.0% (whichever is greater)
%Retic (%)	0.2 – 24.5	0.8 – 26.4	0.7 – 26.3	Maximum deviation: ±5.0%
CSF WBC Low (cells/µL)	0 – 50	0 – 52	0 – 52	Maximum Deviation: ±5 cells/µL
CSF RBC Low (cells/µL)	0 – 50	0 – 46	0 – 51	Maximum Deviation: ±5 cells/µL
CSF RBC High (cells/µL)	50 – 1500	0 – 1509	0 – 1508	Maximum Deviation: ±10%
Body Fluid TNC Low (cells/µL)	0.02 – 400	1 – 542	0 – 618	Maximum deviation: ±10 cells/µL or ±10.0% (whichever is greater)
Body Fluid RBC (10^3cells/µL)	0.1 – 6.76	0 – 7190	0 - 7105	Maximum deviation: ±10x10^3cells/µL or ±10.0% (whichever is greater)

d. Carryover:
Carryover was tested for the WBC, RBC, Hgb, Plt, and retic channels of the system. A carryover set consisted of assaying a high pool followed by 3 aspirations of phosphate buffered saline. The carryover procedure consisted of performing 10 carryover sets. Carryover was tested in configurations 2 and 3, and within each configuration, carryover was tested with the Autosampler (AS), the manual closed tube sampler (MCTS), and the manual opened tube sampler (MOTS). Carryover in the reticulocyte channel was calculated using the RTC-RBC count (i.e. the RBC count derived from the reticulocyte channel). The observed results for the 10 carryover sets met specifications for all parameters, having less than 1% carryover in both configurations.

Parameter / Configuration	**Average % Carryover**		
	ACTS	**MCTS**	**MOTS**
WBC – Configuration 2	0.18	0.33	0.21
WBC – Configuration 3	0.19	0.26	0.17
RBC – Configuration 2	0.14	0.14	0.14
RBC – Configuration 3	0.14	0.14	0.40
Hgb – Configuration 2	0.00	0.00	0.00
Hgb – Configuration 3	0.00	0.00	0.00
PLT – Configuration 2	0.23	0.25	0.22
PLT – Configuration 3	0.82	0.83	0.83
RTC-RBC – Configuration 2	0.14	0.15	0.21
RTC-RBC – Configuration 3	0.14	0.14	0.24

e. Interfering Substances:
Refer to related 510(k) clearances in item 2 above.

f. Background Counts:
Refer to related 510(k) clearances in item 2 above.

2. Other Supportive Instrument Performance Data Not Covered Above:
Not applicable

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.