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

A. 510(k) Number:
k061879

B. Purpose for Submission:
New Instrument with ISE, demonstrating equivalence for use with cleared reagents for Glucose (k880236), and Blood Urea Nitrogen (BUN) (k880078) Repacked for use on Hemodiagnostica's instruments.

C. Measurand:
Glucose
BUN
Sodium (Na^+)
Potassium (K^+)
Chloride (Cl^-)

D. Type of Test:
Glucose and BUN-Quantitative Photometric Assays
Na^+, K^+, and Cl^- Quantitative Ion Selective Electrode Assays

E. Applicant:
Hemodiagnostica, LLC

F. Proprietary and Established Names:
SDI CA480 Clinical Chemistry System

G. Regulatory Information:

1. Regulation section:
   21 CFR §862.1345-Glucose test system.
   21 CFR §862.1770-Urea nitrogen test system.
   21 CFR §862.1665-Sodium test system.
   21 CFR §862.1600-Potassium test system.
   21 CFR §862.1170-Chloride test system.
   21 CFR §862.2160-Discrete Photometric Chemistry Analyzer for Clinical Use
2. Classification:
   II, II, II, II, II, I respectively
3. Product code:
   CFR-Hexokinase, Glucose
   CDN-Urease, Photometric, Urea Nitrogen
   JGS-Electrode, Ion Specific, Sodium
   CEM-Electrode, Ion Specific, Potassium
   CGZ-Electrode, Ion-Specific, Chloride
   JJE-Analyzer, Chemistry (Photometric, Discrete), For Clinical Use
4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See Indication(s) for use below

2. Indication(s) for use:
   The SDI CA480 Clinical Chemistry System includes a discrete, random access, microprocessor controlled clinical chemistry analyzer and dedicated reagents intended for in vitro diagnostic quantitative measurement of Glucose, Blood Urea Nitrogen (BUN), Sodium, Potassium and Chloride in serum. Other various chemistry assays are adaptable to the analyzer.

   Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma. BUN measurements are use in the diagnosis and treatment of certain renal and metabolic diseases. Sodium measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance. Potassium measurements monitor electrolyte balance and are used in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

3. Special conditions for use statement(s):
   For prescription use

4. Special instrument requirements:
   SDI CA480 Clinical Chemistry System

I. Device Description:

The SDI CA480 is a discrete, random access, microprocessor controlled photometric and ISE analyzer with the capability to perform 300 clinical chemistry tests per hour plus 180 electrolyte tests per hour for a total of 480 tests per hour. The product is for use in a clinical capacity as a tool for in vitro diagnostics.

Glucose reagent
Reactive Ingredients:
G-6-PDH (L. mesenteroides),>1000 U/L;
HK (yeast) , >1000 U/L; ATP, 1.0 mmol/L: NAD, 1.5 mmol/L;
0.100 mol/L Tris buffer, pH 7.5

BUN Reagent
Reactive Ingredients:
R1: GLDH (bovine liver), >1000 U/L; α-KG, 7.0 mmol/L;
Urease (jack bean), > 30 KU/L; 0.06 mol/L tris buffer pH 7.8
R2: NADH (yeast), 3.2 mmol/L; buffer

Na^+, K^+, and Cl^- ISE Module

The integrated ISE module is included as a component to the SDI CA480. The ISE module being included has the capability to measure Sodium, Potassium and Chloride. The ISE module utilizes two positions on the sample wheel – a calibrant and a cleaning solution. The ISE module is connected by cable to the CPU of the SDI CA480. Commands to this module are handled by the software of the SDI CA480.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Model 550 Express, Ciba Corning Model 664/FAST 4 System
2. Predicate 510(k) number(s):
   k872302, k871028 respectively
3. Comparison with predicate:
   The SDI CA480 is substantially equivalent to the predicate devices, the Ciba Corning Model 550 Express (for photometric assays) and Ciba Corning Model 664/FAST 4 System (for ISE assays).

	SDI CA480	**Model 550 Express**
510(K) #	New	**k872302**
System Principle	Discrete, random access, multi-test analysis	Discrete photometric clinical chemistry analyzer
Throughput	300 tests per hour	180 test per hour
Configuration	Analytical unit, Control Unit	Analytical Unit, Control Unit
Optical Measurement Unit		
Measurement Modes	Absorbance	Absorbance
Detector	Photo-diode	Photo-diode array
Optical System	Wavelength range of 340 to 700 nm	Wavelength range of 340 to 600 nm
Filters	340,380,405,510,546,578,620, and 700 nm	340, 380, 405, 510, 540, 570, and 600 nm
Linear absorbance range	-.2 – 2.5 A at 340 nm	0 – 2.5 A
Light Source	20 W Halogen lamp	20 W Halogen Lamp
Data Processing		
Calibration curve	Factor, Linear, Logit-log 1, Logit-log 2, Spline, Exponential, Polynomial	Factor, Linear, Qualitative, 1-Logit4, 2-Logit5, 3-Exponential 5, 4-Polynomial5
Cuvettes	Quartz non-disposable cuvettes	Disposable plastic cuvettes
Number of cuvettes	39 (washed between tests)	Rack loaded system
Cuvette washing	Automatic washing system utilizing reagent grade water for washing and forced air / suction for drying	No cuvette washing system
Path length	7 mm	10 mm
Cuvette Volume	600 µL	450 µL
Reagent Volume	500 µL max	400 µL max

	SDI CA480	Model 550 Express
510(K) #	New	**k872302**
Sample/Reagent Delivery		
Pipetting System	Plunger driven by stepping motor	Motorized
Sample Dispense	Sample volume: 3 – 50 µL; 1 µL step	Sample volume: 3 – 30 µL
Reagent Dispense	Reagent 1 volume: 250 – 500 µL Reagent 2 volume: 1 – 250 µL 1 µL step	Reagent Volume: 50 – 400 µL

	SDI CA480	Model 664
510(K) #	New	**k871028**
System Principle	Potentiometric	Potentiometric (for Na, Cl, and K), Thermal Conductivity (for CO2)
Throughput	180 test/hour	270 test/hour (using ISE)
Fluids measured	Whole Serum, Plasma, Diluted Urine	Serum, Plasma, Whole Blood, Urine
Clinical Measurements	Sodium, Potassium, Chloride	Sodium, Potassium, Chloride, Bicarbonate
Electrode Maintenance	disposable (no filling necessary)	Refillable electrode modules
ISE Detector	Potentiometric	Potentiometric
Modes of Analysis	Random Access or STAT	Programmable Batch or STAT
Reagents / Calibrators	Provided Calibrant A and B	All Calibrant (All-Cal)
Cleaning	Provided Cleaning Solution	Wash Solution
Calibration Frequency	Every 30 minutes and by request. One point calibration done on every sample	Every 30 minutes or before a batch run
Sample Volume	60 µL, 160 µL for diluted urine (10:1)	170 µL (batch and stat), 85 µL (microstat)
Pipetting System	Probe driven by stepper motor	Motorized probe
Fluid Verification	Optical fluid detection with bubble detection capability	Optical fluid detection
Sample Dispensing	Aspiration and dispensation into ISE module	Aspiration from sample cup into fluidic/measurement system, no dispensing

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

None referenced

L. Test Principle:

Glucose

Glucose in the serum sample is phosphorylated by hexokinase using excess adenosine triphosphate (ATP) in the presence of magnesium ions to glucose-6-phosphate. Glucose-6-phosphate is oxidized in the presence of nicotinamide adenine dinucleotide (NAD) by glucose-6-phosphate dehydrogenase (G-6-PDH) to 6-phosphogluconate and NADH which is measured at 340 nm and is proportional to the amount of glucose present.

BUN
Urea is converted to ammonia and CO_2 by the enzyme urease. The ammonia produced is utilized by glutamate dehydrogenase (GLDH) to convert alpha-ketoglutarate (α-KG) to glutamic acid, with the concomitant conversion of NADH to NAD which is measured at 340 nm, and is proportional to the amount of BUN present.

Sodium, Potassium and Chloride
The ISE Module of the SDI CA480 utilizes Ion Selective Electrode technology. The flow-through Sodium electrode uses selective membrane tubing, formulated to be sensitive to Sodium ions. The Potassium and Chloride electrodes employ similar designs with appropriate selective membrane materials. The potential of each electrode is measured relative to a fixed, stable voltage established by the double-junction silver / silver chloride reference electrode. An ion selective electrode develops a voltage that varies with the concentration of the ion to which it responds. The relationship between the voltage developed and the concentration of the sensed ion is logarithmic, as expressed by the Nernst equation:

$$Ex = Es + \frac{nF}{RT} \log(C\alpha)$$

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:

Within-Run and Total Precision studies were carried out two levels of sera were prepared based on medical decision levels.
Within-run (Repeatability) data were generated according to CLSI procedure (EP-05)

Glucose Precision:

Within Run n=40	Level 1	Level 2	Level 3
Mean (mg/dL)	50.5	112	296
S.D. (mg/dL)	1.19	1.21	2.75
C.V. (%)	2.36	1.08	0.93
Total n=50	(5 days / 2 runs per day / 5 samples per run)		
Mean (mg/dL)	50.47	113.22	296.69
S.D. (mg/dL)	1.45	1.01	2.14
C.V. (%)	2.88	0.89	0.72

BUN Precision:

Within Run n=20	Level 1	Level 2
Mean (mg/dL)	10.3	19.95
S.D. (mg/dL)	0.98	1.00
C.V. (%)	9.50	5.01
Total n=50	(5 days / 2 runs per day / 5 samples per run)	
Mean (mg/dL)	9.66	21.17
S.D. (mg/dL)	0.79	1.19
C.V. (%)	8.13	5.62

	Within-Run		**Total**	
Sodium	**Level 1**	**Level 2**	**Level 1**	**Level 2**
	n = 20		n = 50	
Mean	134.50	161.35	130.64	160.91
SD	1.05	0.59	1.78	1.90
C.V (%)	0.78%	0.36%	1.37%	1.18%
Range	133 -	160 -	128.5- 135.5	156.5 -

	Within-Run		**Total**	
Potassium	**Level 1**	**Level 2**	**Level 1**	**Level 2**
	n = 20		n = 50	
Mean	2.94	6.02	3.00	6.02
SD	0.07	0.07	0.11	0.10
C.V (%)	2.54%	1.16%	3.74%	1.74%
Range	2.8 -3.1	5.9 -	2.8 - 3.25	5.75 -

	136	162	164	6.1	6.3

	Within-Run		Total	
Chloride	**Level 1**	**Level 2**	**Level 1**	**Level 2**
	n = 20		n = 50	
Mean	74.85	110.75	74.82	111.88
SD	1.27	1.45	1.10	1.36
C.V (%)	1.69%	1.31%	1.47%	1.22%
Range	73 - 77	109 - 115	72 - 77.5	108.5 - 114.5

b. Linearity/assay reportable range:

The measurement range for glucose is 3 to 550 mg/dL
The measurement range for BUN is 4 mg/dL to105 mg/dL.
The measurement range for Sodium is 100 to 170 mmol/L
The measurement range for Potassium is 2.0 to 7.0 mmol/L
The measurement range for Chloride is 65 to 120 mmol/L

The linearity study was performed according to CLSI guidance using commercially available linearity material

GLU Linearity Limit 550

List No.	Published Values	Observed Values				Mean	2 * S.D.	Recovery
		Run 1	Run 2	Run 3	Run 4			
9201	25.0	27.0	26.0	26.0	28.0	26.75	1.91	107.00%
9202	200.0	203.0	202.0	204.0	203.0	203.00	1.63	101.50%
9203	375.0	379.0	378.0	380.0	379.0	379.00	1.63	101.07%
9204	550.0	561.0	560.0	560.0	562.0	560.75	1.91	101.95%
9205	725.0	742.0	745.0	744.0	745.0	744.00	2.83	102.62%
						Avg. Recovery		102.83%

BUN Linearity Limit 105

No.	Published Values	Observed Values				Mean	2 * S.D.	Recovery
		Run 1	Run 2	Run 3	Run 4			
9201	5.0	5.0	5.0	4.0	5.0	4.75	1.00	95.00%
9202	37.5	37.0	38.0	38.0	38.0	37.75	1.00	100.67%
9203	70.0	71.0	72.0	72.0	73.0	70.00	1.63	100.00%
9204	102.5	104.0	103.0	105.0	104.0	104.00	1.63	101.46%
9205	135.0	138.0	136.0	138.0	138.0	137.50	2.00	101.85%
						Avg. Recovery		99.80%

Sodium		Linearity Limit			160	160		
List No.	Published Values	Observed Values				Mean	2 S.D.	Recovery
		Run 1	Run 2	Run 3	Run 4			
9201	100	104	103	104	104	103.75	1.00	103.75%
9202	118	120	120	121	118	119.75	2.52	101.48%
9203	136	138	138	138	138	138.00	0.00	101.47%
9204	154	151	156	156	156	154.75	5.00	100.49%
9205	172	174	173	173	171	172.75	2.52	100.44%
						Avg. Recovery		101.53%

Potassium		Linearity Limit			6.5	6.5		
List No.	Published Values	Observed Values				Mean	2 S.D.	Recovery
		Run 1	Run 2	Run 3	Run 4			
9201	1.75	1.80	2.00	1.80	1.90	1.88	0.19	107.14%
9202	4.50	4.30	4.30	4.40	4.50	4.38	0.19	97.22%
9203	7.25	6.90	7.10	7.00	7.30	7.08	0.34	97.59%
9204	10.00	9.70	9.90	9.80	10.00	9.85	0.26	98.50%
9205	12.75	12.50	12.60	12.60	12.50	12.55	0.12	98.43%
						Avg. Recovery		99.78%

Chloride		Linearity Limit			120	120		
List No.	Published Values	Observed Values				Mean	2 S.D.	Recovery
		Run 1	Run 2	Run 3	Run 4			
9201	60.0	60.0	62.0	61.0	62.0	61.25	1.91	102.08%
9202	88.5	89.0	90.0	90.0	90.0	89.75	1.00	101.41%
9203	117.0	118.0	118.0	119.0	120.0	118.75	1.91	101.50%
9204	145.5	145.0	144.0	145.0	145.0	144.75	1.00	99.48%
9205	174.0	177.0	175.0	176.0	175.0	175.75	1.91	101.01%
						Avg. Recovery		101.10%

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Traceability information for the assays was reviewed under k880236 for Glucose, k880078 for BUN and k000926 for Sodium, Potassium and Chloride.

d. *Detection limit:*
Glucose
A calibration factor of approximately 750 was obtained, which is equivalent to

an analytical sensitivity of 1.33 ΔmAbs per mg/dL.

Limit of Detection:
10 samples containing no analyte were measured and the LoD calculated. The Limit of Detection for Glucose was found to be 3 mg/dL.

Limit of Quantitation:
40 samples containing known low amount of analyte were measured.
Precision was evaluated, with a maximum C.V. (%) of 20% allowed.
The Limit of Quantitation for Glucose was found to be 3 mg/dL.

BUN
A calibration factor of approximately 796 was obtained, which is equivalent to a sensitivity of 1.26 ΔmAbs per mg/dL.

Limit of Detection:
10 samples containing no analyte were measured and the LoD calculated.
The Limit of Detection for BUN was found to be 4 mg / dL.

Limit of Quantitation:
40 samples containing known low amount of analyte were measured.
Precision was evaluated, with a maximum C.V. (%) of 20% allowed.
The Limit of Quantitation for BUN was found to be 4 mg /dL.

ISE
The calibration factor for each assay is 1000, which gives a sensitivity of 1.00 ΔmAbs per mmol / dL.

The ISE measurable range is based on linearity studies only.

e. Analytical specificity:

Glucose

Hemoglobin:
Hemolyzed sample (> 200mg/dL hemoglobin) will interfere with this assay.
Bilirubin:
No significant interference (±10%) from bilirubin up to 6.0 mg/dL.
Lipemia:
Lipemic samples (> 275 mg/dL) measured as triglycerides will interfere with this assay.

BUN

Hemoglobin:
No significant interference (±10%) from hemoglobin up to 200 mg/dL.
Bilirubin:
Samples with high Bilirubin (> 3.5 mg/dL) will interfere with this assay.
Lipemia:

No significant interference (±10%) from triglyceride up to 250 mg/dL.

ISE

Hemoglobin:

Hemoglobin shows interference with potassium. Do not use hemolyzed samples for potassium. No significant interference from hemoglobin on sodium and chloride up to 2000mg/dL.

Lipemia:

No significant interference from lipemia up to 1000mg/dL measured as triglycerides on sodium, potassium or chloride.

Bilirubin:

No significant interference from Bilirubin up to 31mg/dL on sodium, potassium or chloride.

For a comprehensive review of drug interference see Young, et al[1].

f. Assay cut-off:

Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison was performed between the SDI CA480 and the predicate Ciba Corning Express 550 (for BUN and Glucose) and Ciba Corning 664 (for Na, K, and Cl) according to CLSI protocols across the claimed assay ranges. Linear regression results are summarized below:

Analyte	n	r	y =	Range
BUN	60	0.9988	y = 0.933x + 0.94	4 - 105
Glucose	67	0.9998	y = 0.981x + 0.99	4 - 559
Sodium	60	0.9905	y = 0.998x -1.26	86 - 173
Potassium	60	0.9946	y = 0.977x + 0.06	1.6 - 7.1
Chloride	60	0.9761	y = 1.019x -2.34	64 - 125

b. Matrix comparison:

Not Applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable

b. Clinical specificity:

Not Applicable

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

Not Applicable

4. Clinical cut-off:

Not Applicable

[1] Young, D.S., et al, Clin. Chem. 21:1D (1975)

5. Expected values/Reference range:
   Glucose: 70 - 105 mg/dL
   BUN: 7 - 18 mg/dL
   Sodium: 136 - 145 mmol/L
   Potassium: 3.5 - 5.1 mmol/L
   Chloride: 98 - 107 mmol/L
   References from Tietz, N.W., Fundamentals of Clinical Chemistry, 2nd ed., .B. Saunders Co., Philadelphia, p. 2190, (1994)

N. Instrument Name:

Hemodiagnostica, SDI CA480 Chemistry Analyzer

O. System Descriptions:

1. Modes of Operation:
   Random Access or STAT modes
2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
   Yes ___X_____ or No _____
3. Specimen Identification:
   Manual entry, Worklist downloads and Bar Code
4. Specimen Sampling and Handling:
   Direct primary tube sampling or sample cups
5. Calibration:
   Photometric Calibration curves:
   Factor, Linear, Logit-log 1, Logit-log 2, Spline, Exponential, and Polynomial

   ISE Potentiometric Calibrant A and B, every 30 minutes and by request. One point calibration done on every sample.
6. Quality Control:
   Analyzer has a Quality Control program to monitor assay trends.

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

None

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.