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

A. 510(k) Number:
k101741

B. Purpose for Submission:
To obtain clearance for a discrete photometric analyzer with ISE module and glucose reagent and Ion Selective Electrode (ISE) Module for Sodium, Potassium and Chloride

C. Measurand:
Glucose
Sodium
Potassium
Chloride

D. Type of Test:
Glucose – Quantitative Photometric
Sodium – ISE
Potassium – ISE
Chloride – ISE

E. Applicant:
Diatron Group

F. Proprietary and Established Names:
Diatron Pictus 400

G. Regulatory Information:

1. Regulation section:
   21CFR Sec.- 862.1345: Glucose test system.
   21CFR Sec.- 862.1600: Potassium test system.
   21CFR Sec.- 862.1170: Chloride test system.
   21CFR Sec.- 862.1665: Sodium test system.
   21CFR Sec.- 862.2160: Discrete photometric chemistry analyzer for clinical use.

2. Classification:
   II, II, II, II, I respectively

3. Product code:
   CGA - Glucose Oxidase, Glucose
   CEM - Electrode, Ion Specific, Potassium
   CGZ - Electrode, Ion-Specific, Chloride
   JGS - Electrode, Ion Specific, Sodium

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:

   Autoanalyzer Pictus 400 is designed for Clinical Laboratory Use, with direct determination of Na, K, Cl in serum, and Glucose in serum, and to measure a variety of analytes that may be adaptable to the analyzer depending on the reagent used.

   Sodium measurements are used for monitoring electrolyte imbalances. Potassium measurements are used for diagnosis in diseases with high and low Potassium levels. Chloride measurements are primarily use to detect and treatment of metabolic disorders. 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.

3. Special conditions for use statement(s):
   Prescription use

4. Special instrument requirements:
   Diatron PICTUS 400

I. Device Description:

Clinical Chemistry analyzer designed for clinical laboratory use, making direct quantitative measurements of Na^+ (Sodium), K^+ (Potassium), Cl^- (chloride) in serum and Glucose in serum samples. Additionally, other various chemistry assays may be performed in the analyzer, provided that suitable reactions generating color or variation of color are used. It consists in five modules: control, samples dispensing, photometric readings, Ion Selective module, printout and presentation of the information.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Trace Glucose
   Medica ISE Module
   DataPro Clinical Chemistry Analyzer
2. Predicate 510(k) number(s):
   k980026, k070531, k042767 respectively

3. Comparison with predicate:

	Feature	PICTUS 400	DataPro (includes all predicates)	Similarities/ Differences
	510(k)	Pending	k042767; k070531; k980026	
1	Indication(s) for use	Autoanalyzer Pictus 400 is designed for Clinical Laboratory Use, with direct determination of Na, K, Cl in serum and plasma samples, and Glucose in serum, and to measure a variety of analytes that may be adaptable to the analyzer depending on the reagent used.	Same	
2	System Principles			
	QC/Calibration	Automatic and Manual	Automatic and Manual	Same
	LIS external connectivity	YES	YES	Same
	Barcode	Samples and Reagents	Samples	Different
	Redilution on abnormals	YES	YES	Same
3	Throughput			
		280 test/hour 400 with ISE	240 test/hour 360 with ISE	Different
4	Principle of analysis			
	Mode of detection	Photometric	Photometric	Same
	Analytical Methods	Endpoint with sample blanking	Endpoint with sample blanking	Same
	Calibration	Linear and non linear	Linear and non linear	Same

	Feature	PICTUS 400	DataPro (includes all predicates)	Similarities/ Differences
5	Optical measurement unit Measurement modes			
		Absorbance	Absorbance	Same
	Optical modes	Bichromatic, turbidimetric	Bichromatic, turbidimetric	Same
	Wavelengths	330 nm, 405 nm, 450 nm, 505 nm, 550 nm, 570 nm, 600 nm, 650 nm , 700 nm	330 nm, 405 nm, 450 nm, 505 nm, 550 nm, , 600 nm, 650 nm , 700 nm, 750 nm	Different
	Linear absorbance range	-0,1 to 3,6	-0,1 to 3,6	Same
	Light source	Tungsten halogen	Tungsten halogen	Same
	Detector	photodiode	photodiode	Same
6	Reaction unit			
	Reaction cuvettes	Plastic semi-disposables	Plastic semi-disposables	Same
	Reaction volume	180 to 700 ul	180 to 700 ul	Same
	Path length	6 mm	6 mm	Same
	Temperature	Room, 30°C, 37°C	Room, 30°C, 37°C	Same
7	Sample and reagent unit			
	Reagent positions	48	48	Same
	Sample positions	48	48	Same
	Pipettor system	Syringe, motor driven	Syringe, motor driven	Same
	Mixing	Motor in probe, tray shake	Tray shake	Different
	Reagent refrigerator	YES	YES	Same
	Sample dispensing	2 -50 microliters	2 -50 microliters	Same
8	Power			
		85 230 VAC 400 VA	85 230 VAC 400 VA	Same

	Feature	PICTUS 400	DataPro (includes all predicates)	Similarities/ Differences
9	Environmental conditions	15 to 30 ^{o}C, max Hum. 80%	15 to 30 ^{o}C, max Hum. 80%	Same
10	ISE Principle	Ion selective, direct reading	Ion selective, direct reading	Same
11	ISE sample type	Serum	Serum	Same
12	Available tests	Na, K, Cl	Na, K, Cl	Same
13	ISE calibration	Two-point and single point	Two-point and single point	Same
14	Sample size	70 ul	70 ul	Same

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

None were referenced.

L. Test Principle:

Glucose - The DIATRON glucose hexokinase method is based on hexokinase and glucose-6-phosphate dehydrogenase to catalyze the reaction. Glucose is phosphorylated with adenosine triphosphate (ATP) in the reaction catalyzed by hexokinase (HK). The product, glucose-6-phosphate (G6P) is then oxidized with the associated reduction of nicotinamide adenine dinucleotide (NAD) to NADH in the reaction catalyzed by glucose-6-phosphate-dehygrogenase (G6PDH). The formation of NADH causes an increase in absorbance at 340 nm. The increase is directly proportional to the amount of glucose in the sample.

The Medica Electrolyte Measurement System – ISE methodology using a flow-through sodium electrode uses selective membrane tubing, specially 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.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>
   a. Precision/Reproducibility:

Precision: Glucose			
Within Run	Level 1	Level 2	Level 3
Mean (mg/dL)	49	95.7	284.9
S.D. (mg/dL)	0.5	1	1.4
C.V. (%)	1	1	0.5
Total			
S.D. (mg/dL)	2.2	1.8	3.9
C.V. (%)	4.5	1.9	1.4
Precision: Na (Sodium)			
Within Run	Level 1	Level 2	Level 3
Mean (mmol/L)	123.31	144.52	182.0
S.D. (mmol/L)	1.302	1.110	0.9
C.V. (%)	1.06	0.77	0.5
Day to Day			
S.D. (mmol/L)	0.720	0.933	1.5
C.V. (%)	0.580	0.65	0.4
Precision: K (Potassium)			
Within Run	Level 1	Level 2	Level 3
Mean (mmol/L)	2.46	3.69	5.43
S.D. (mmol/L)	0.03	0.037	0.662
C.V. (%)	1.00	0.99	1.15
Day to Day			
S.D. (mmol/L)	0.05	0.015	0.058
C.V. (%)	2.0	0.40	1.05
Precision: Cl (Chloride)			
Within Run	Level 1	Level 2	Level 3
Mean (mmol/L)	85.44	103.54	141.4
S.D. (mmol/L)	0.894	0.858	0.8
C.V. (%)	1.5	0.83	0.6
Day to Day			

S.D. (mmol/L)	0.623	1.542	1.6
C.V. (%)	0.73	1.49	1.1

b. *Linearity/assay reportable range:*

Glucose reportable range (10 to 500 mg/dL) is determined based on measuring the linearity across the measuring range.

The reportable range for ISE measurements are based on linearity using 9 reference samples covering the reportable range.

ISE	Linearity/ reportable	Slope	Intercept	R^2
Na (Sodium)	115-196 mmol/L	1.0634	-4.7572	0.9993
K (Potassium)	1.1-8.8 mmol/L	0.9907	-0.1277	0.9992
CL (Chloride)	49-152 mmol/L	1.0355	-4.2089	0.9987

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
See k980026 for information concerning Glucose and k070531 for ISE

d. *Detection limit:*
Glucose - The Limit of Quantitation (LOQ) of 10 mg/dL was established using a low sample measured a total 90 times over 3 days giving a CV of less than 20%.
ISE – Not Applicable

e. *Analytical specificity:*

Glucose - Studies to determine the level of interference for hemoglobin, bilirubin, and lipemia were carried out, the following results were obtained:

- Hemoglobin: Use fresh non-hemolyzed serum removed from the clot as soon as possible.
- Bilirubin: No significant interference (•10%) from bilirubin up to 9.0 mg/dL.
- Lipemia: No significant interference (•10%) from lipemia up to 414 mg/dL measured as triglycerides.

ISE - Studies to determine the level of interference for hemoglobin, bilirubin, and lipemia were carried out the following results were obtained:

- 10% Change or 3 units if within 10% up to:

	Hemolysis	Lipemia	Bilirubin
Na (Sodium)	400 mg/dL	1036 mg/dL	20.9 mg/dL
K (Potassium)	800 mg/dL	1036 mg/dL	28.9 mg/dL
CL (Chloride)	300 mg/dL	1036 mg/dL	23.8 mg/dL

A number of drugs and substances may affect the accuracy of Glucose Sodium, Potassium, and Chloride. See Young, D.S. et al, Clin. Chem. 21:1D (1975).

f. Assay cut-off:
Not Applicable

2. Comparison studies:
   a. Method comparison with predicate device:

Serum Glucose
Number of samples: 62
Range of samples: 28-499 (mg/dL)
Correlation Coefficient: 0.9978
Slope: 0.9764
Intercept: 9.4 (mg/dL)

Serum Sodium
Number of samples: 41
Range of samples: 116 – 189 (mmol/L)
Correlation Coefficient: 0.9863
Slope: 1.030
Intercept: 0.7 (mmol/L)

Serum Potassium
Number of samples: 46
Range of samples: 2.1 – 8.4 (mmol/L)
Correlation Coefficient: 0.9803
Slope: 1.01
Intercept: -0.11(mmol/L)

Serum Chloride
Number of samples: 46
Range of samples: 61 – 151 (mmol/L)
Correlation Coefficient: 0.9908
Slope: 1.088
Intercept: -7.9 (mmol/L)

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

5. Expected values/Reference range:

Glucose[1]	70 – 105 mg/dL
ISE[2]	Suggested Reference Range
Na (Sodium)	136 - 145 mmol/L
K (Potassium)	3.5 - 5.1 mmol/L
CL (Chloride)	98- 107 mmol/L

[1]Tietz, N.W., Fundamentals of Clinical Chemistry, 2nd ed., W.B. .Saunders Co., Philadelphia, p.243, (1976).
[2]Tietz, N.W. Clinical Guide to Laboratory Tests, Philadelphia, W.B. Saunders, (1990).

N. Instrument Name:

Pictus 400

O. System Descriptions:

1. Modes of Operation:

   Random access

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?:

   Yes __X__ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?:

Yes _____ or No __X__

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:

   Barcoded

4. Specimen Sampling and Handling:

   48 position sample tray

5. Calibration:

   Automatic and Manual

6. Quality Control:

   Automatic and Manual

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.