



Food and Drug Administration
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DIATRON US, INC.
C/O ERIKA AMMIRATI
PRESIDENT
575 SHIRLYNN COURT
LOS ALTOS CA 94022

January 14, 2016

Re: K151487

Trade/Device Name: Diatron ISE,
Diatron Glucose Hexokinase Method
Diatron Pictus 700 Clinical Chemistry Analyzer
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CFR, JGS, CEM, CGZ, JJE
Dated: November 30, 2015
Received: December 1, 2015

Dear Erika Ammirati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151487

Device Name

Diatron Glucose Hexokinase Method

Diatron ISE

Diatron Pictus 700 Clinical Chemistry Analyzer

Indications for Use (Describe)

Diatron Glucose Hexokinase Method is for the in vitro quantitative determination of Glucose in serum for use with Diatron Pictus 700 Chemistry Analyzer. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes.

Diatron ISE is for the in vitro quantitative determination of Sodium (Na⁺), Potassium (K⁺), and Chloride (Cl⁻) concentrations in serum on the Diatron Pictus 700 Chemistry Analyzer. Sodium measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance. Potassium measurements are used in monitoring electrolyte balance and in the diagnosis and treatment of diseases/conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

The Diatron Pictus 700 Clinical Chemistry Analyzer is a wet-chemistry analyzer for the direct determination of sodium, potassium, chloride and glucose concentrations in serum, and to measure a variety of analytes that may be adaptable to the analyzer depending on the reagent used. It is for in vitro diagnostic use.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K151487.

807.92 (a)(1): Name: Diatron, US, Inc.
Address: 2304 W 78th Street
Hialeah, FL 33016
Phone: 877-684-1139
FAX: 913-344-9958
Contact: Mr. Frank Matusazak

807.92 (a)(2): Device name- trade name and common name, and classification

Trade Name: Diatron ISE, Diatron Glucose Hexokinase Method
Diatron Pictus 700 Clinical Chemistry Analyzer

Common Name: Routine chemistry analyzer for glucose, and ISE technology for sodium, potassium, and chloride

Classification Name(s):

21 CFR § 862.1345- Glucose 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

807.92 (a)(3): Identification of the legally marketed predicate devices

Diatron Pictus 400 – K101741

807.92 (a)(4): Device Description

The Pictus 700 Clinical Chemistry Analyzer is an automatic, floor-standing, wet chemistry system, designed for the qualitative and quantitative analyses of various diagnostic test systems. This premarket notification is for the direct quantitative measurements of Na⁺ (sodium), K⁺ (potassium), Cl⁻ (chloride) and glucose in serum samples. Additionally, other types of chemistry assays may be performed on the analyzer, provided that suitable color-generating reactions or reactions with variation of color are used. The system is intended for use in clinical laboratories.

The instrument consists of an analyzer unit and an operations computer with a screen that allows the user to input commands for system operation and data display. The analyzer unit includes two temperature-controlled incubation rotors and a multi-wavelength photometer, a cooled carousel for loading barcoded sample tubes or micro cups and reagent cartridges, and two probes that deliver reagents and samples to the incubation rotors and the ISE measurement flow cell. The analyzer unit also houses containers for wash solution and waste. An ISE module, installed on the analyzer unit, is used to measure sodium, potassium and chloride ionic activity in serum.

2304-10 West 78th Street

Hialeah, Fl 33016

1-877-684-1139



System operation:

After a sample tube or cup is placed into the carousel, and appropriate reagents have been installed and properly calibrated, the operator programs a test request. The analyzer pipettes reagent(s) and the sample, at appropriate volumes and times dictated by the test application stored in the analyzer memory, and mixes (stirs) the sample and reagent together. After the sample and reagent react in the incubator, the analyzer measures the absorbance of the test solution at wavelengths dictated by the test application, and, based on the absorbance readings, it calculates the concentration of analyte in the sample using appropriate mathematical formulas dictated by the test application. The test system can measure analytes in serum and results are available in approximately 2 minutes for the electrolyte tests and 10 minutes for glucose determinations.

Chemistry reactions:

Sodium, Potassium and Chloride.

The ISE module measures sodium, potassium, and chloride in serum using ion-selective electrode technology. The electrodes are flow-through and use selective membranes, especially formulated to be sensitive to sodium, potassium, and chloride ions. The electric potential of each electrode is measured relative to a fixed, stable voltage established by a double-junction silver/silver chloride reference electrode. The voltage developed varies with the concentration of the corresponding ion logarithmically, as expressed by the Nernst equation.

The method of measurement is comparative. First, the ISE module measures the potentials developed when the sample is positioned in front of the electrodes. Next, Calibrant A is positioned in front of the electrodes. The difference between the two potentials is related logarithmically to the concentration of the measured ions in the sample, divided by their respective concentrations in the calibrant solution. Since the difference in potentials and the concentration of the sodium, potassium, and chloride ions in the calibrant solution are known, the computer can calculate the concentration of the ions in the sample.

Glucose:

The concentration of glucose in serum is performed enzymatically, according to the hexokinase method, based on the following reactions: b,D-glucose in the sample reacts with adenosine triphosphate (ATP) under the catalytic action of hexokinase, to produce glucose 6-phosphate and adenosine diphosphate (ADP). Glucose 6-phosphate consequently reacts with oxidized nicotinamide-adenine nucleotide (NAD⁺) to produce D-gluconic acid 6-phosphate and reduced nicotinamide-adenine nucleotide (NADH), under the catalytic action of glucose-6-phosphate dehydrogenase (G-6PDH).

The reduced nucleotide (NADH) absorbs strongly at 340 nm, whereas its oxidized form (NAD⁺) does not. The difference in absorbance between the final reading and the blank, monitored bichromatically at 340 nm and 380 nm, is directly proportional to the concentration of b,D-glucose in the sample. The analyzer photometer reads the absorbance at 340 nm and 380 nm at time intervals dictated by the glucose application stored in the analyzer memory, and the change in absorbance is calculated automatically.



807.92 (a)(5): Intended Use

Diatron Glucose Hexokinase Method is for the in vitro quantitative determination of Glucose in serum for use with Diatron Pictus 700 Chemistry Analyzer. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes.

Diatron ISE is for the in vitro quantitative determination of Sodium (Na⁺), Potassium (K⁺), and Chloride (Cl⁻) concentrations in serum on the Diatron Pictus 700 Chemistry Analyzer. Sodium measurements are used in the diagnosis and treatment of diseases involving electrolyte imbalance. Potassium measurements are used in monitoring electrolyte balance and in the diagnosis and treatment of diseases/conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

The Diatron Pictus 700 Clinical Chemistry Analyzer is a wet-chemistry analyzer for the direct determination of sodium, potassium, chloride and glucose concentrations in serum, and to measure a variety of analytes that may be adaptable to the analyzer depending on the reagent used. It is for in vitro diagnostic use.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

The following chart describes similarities and differences between the two test systems.

Characteristic	Candidate System (k151487) Diatron Pictus 700 Analyzer	Predicate System Pictus 400, k101741
<i>Instrument Platform</i>	Pictus 700	Pictus 400
Mode of Detection	Photometric	Same
Photometric Detector	Photodiode	Same
Optical Modes	Monochromatic, Bi-chromatic,	Same
Analytical Measure	Endpoint and kinetic with sample blanking	Same
Wavelengths	340, 380, 405, 450, 490, 505, 550, 590, 620, 650, 700, 750	330, 405, 450, 505, 550, 570, 600, 650, 700
# of Photometer Filters	12	9
Linear Absorbance Range	-0.1 to 3.6	Same
Photometric Tests/Hour	600	280
Reagent Volume Range	180 to 700 microliters	Same
Reagents On-board Capacity	72	48
Sample On-board Capacity	95	48
Device Class, Regulation Code, Product Code	Class I, 21 CFR 862.2160 (discrete photometric chemistry analyzer), JJE	Same
<i>ISE Test System, Glucose System</i>		
Device Class, Regulation Code	Class II, Sodium- 21 CFR 862.1665 Potassium- 21 CFR 862.1600 Chloride- 21 CFR 862.1170 Glucose, 21 CFR 862.1345	Same

Characteristic	Diatron Pictus 700 Analyzer	Predicate-Pictus 400, K101741
Classification Product Code	Sodium- JGS Potassium- CEM Chloride- CGZ Glucose- CFR	Same
Intended Use	Quantitative determinations of sodium, potassium, and chloride using ion selective electrodes, and glucose by photometry in serum.	Same
Testing Environment	Clinical lab	Same
Test Principle	ISE potentiometry (electrolytes) and photometry (glucose)	Same
Specimen Type	Human serum	Human serum, plasma, or urine
<u>Method Comparisons</u> (Correlation coefficients, # of Samples, Testing Ranges) [mmol/L: ISE, mg/dL: glucose]	Sodium-0.995 (69, 120-181) Potassium-0.998 (69, 1.7-8.7) Chloride-0.997 (69, 55-134) Glucose - 0.999 (136, 26 to 484)	Sodium-0.986 (41, 116-189) Potassium-0.980 (46, 2.1-8.4) Chloride-0.991 (46, 61-151) Glucose - 0.976 (62, 28-499)
Linearity/Reportable Ranges	Sodium- 115-196 mmol/L Potassium- 1.1-8.8 mmol/L Chloride- 49-152 mmol/L Glucose- 13-500 mg/dL	Sodium- 115-196 mmol/L Potassium- 1.1 to 8.8 mmol/L Chloride- 49-152 mmol/L Glucose 10-500 mg/dL
Sensitivity-Detection Limits (ISE Functional Sensitivity, Glucose- standard LOB/LOD)	Sodium- 27.6 mmol/L @ 3.02%CV Potassium-1.05 mmol/L @ 0%CV Chloride- 14.8 mmol/L @ 3.02%CV Glucose 7 mg/dL @ 2.6%CV	N/A N/A N/A N/A
Within-run Precision (across 3 levels- low, middle, high)	%CV Ranges Sodium- 0.4 to 0.5%CV Potassium-0.00 to 0.78 %CV Chloride-0.5 to 0.6 %CV Glucose-0.9 to 1.6 %CV	%CVs Ranges: Sodium- 0.50 to 1.06 %CV Potassium- 0.99 to 1.15 %CV Chloride- 0.60 to 1.50 %CV Glucose- 0.50 to 1.00%CV
Between-run (Total) Precision	%CV Ranges Sodium-0.9-1.4 %CV Potassium-1.05-1.65 %CV Chloride- 0.8-1.2 %CV Glucose- 3.0-3.2 %CV	%CVs ranges: Sodium- 0.40 to 0.65 %CV Potassium- 0.40 to 2.00 %CV Chloride- 0.73 to 1.49 %CV Glucose- 1.40 to 4.50 %CV

807.92 (b)(1): Brief Description of Nonclinical Data

Limits of detection/functional sensitivities:

For the glucose assay, conventional LoB/D/Q testing was performed according to CLSI EP17-A2; the LoQ was measured as 7 mg/dL.

For functional sensitivity, normal sample pools were serially diluted nine times in 10% increments (total of 10 samples), and, 5 replicates per dilution were measured for each test system. Mean values of results were calculated for each dilution, and were compared to the calculated ion activities or glucose concentrations. The highest dilution (lowest concentration) with less than 10 %CV was compared to the low linearity claim. Acceptable results were those where the highest dilution concentration was lower than, or equal to, the low-end linearity claim.



Sodium: Functional Sensitivity

The 1:9 dilution, resulting in sodium ion activity of 27.6 mmol/L, corresponded to a %CV of 3.02%; therefore, the low end claim of linearity of 110 mmol/L was verified.

Potassium: Functional Sensitivity

At all dilutions, the %CVs were substantially lower than the 10% maximum. Even at the 1:10 dilution, resulting in potassium ion activity of 1.05 mmol/L, the CV was 0.00%; therefore, the low end claim of linearity from 1.0 mmol/L was verified.

Chloride: Functional Sensitivity

The 1:9 dilution, resulting in chloride ion activity of 14.8 mmol/L, corresponded to a %CV of 3.02%; therefore, the low end claim of linearity from 50 mmol/L was verified.

Glucose: EP protocol. LOB/LOD/LOQ - Glucose depleted samples

Testing the neat sample, depleted of Glucose y standing > 24 hrs exposed to red cells in the sample draw. The LOQ CV was 1.3%. This verified the low end LOD and LOQ claim of 7 mg/dL.

Linearity:

Eleven levels of each analyte were tested. The samples were assigned their reference values arithmetically from the labeled values and were tested in duplicate by the Pictus 700. The mean Pictus (y-axis) were plotted against the assigned values (x-axis). The acceptance criteria are described below.

Acceptance Criteria:

- Sodium: +/- 10% and or +/- 5 mmol/L
- Potassium +/- 10% and or +/- 1.0 mmol/L
- Chloride: +/- 10% and or +/- 5 mmol/L
- Glucose: +/- 10% and or +/- 5 mg/dL

Sodium- The assay is linear from 13 mmol/L to 196 mmol/L. The claimed range will be 115 to 196 mmol/L.

Potassium- The assay is linear from 0.9 to 12.8 mmol/L. The claimed range will be 1.1 to 8.8 mmol/L.

Chloride- The assay is linear from 41 mmol/L to 200 mmol/L. The claimed range will be 49 mmol/L to 152 mmol/L.

Glucose- The assay is linear from 13 mg/dL to 632 mg/dL. The claimed range will be 13 to 500 mg/dL.

Precision:

Following CLSI EP5-A2, control samples (low, middle, and high levels) were tested in duplicate, twice a day, for 20 days, for a total of 80 results per level. The results were tabulated and the data were analyzed for means and percent coefficient of variation (%CVs).



Sodium values for each level assayed on the Pictus 700 Analyzer

	Mean	Within-run %CV	Total %CV
Low Level	126 mmol/L	0.6%	0.9%
Med. Level	143 mmol/L	0.5%	1.4%
High Level	159 mmol/L	0.7%	1.0%

Potassium values for each level assayed on the Pictus 700 Analyzer

	Mean	Within-run %CV	Total %CV
Low Level	3.4 mmol/L	0.00%	1.05%
Med. Level	4.5 mmol/L	0.00%	1.65%
High Level	5.8 mmol/L	0.78%	1.41%

Chloride values for each level assayed on the Pictus 700 Analyzer

	Mean	Within-run %CV	Total %CV
Low Level	87 mmol/L	0.6%	0.9%
Med. Level	98 mmol/L	0.5%	1.2%
High Level	109 mmol/L	0.5%	0.8%

Glucose values for each level assayed on the Pictus 700 Analyzer

	Mean	Within-run %CV	Total %CV
Low Level (45)	45 mg/dL	1.6%	3.2%
Med. Level (92)	92 mg/dL	0.9%	3.0%
High Level (309)	309 mg/dL	1.2%	3.1%

Interferences:

The study evaluated increasingly higher levels of: bilirubin, hemoglobin, and triglycerides for all parameters. A two-level control set with low and high levels of each analyte was spiked to seven or eight levels (depending on the interferent) and the spiked samples plus the neat samples were tested in duplicates by the Pictus 700 using its standard operating procedure; the results were averaged. In each case, the spiked sample result mean was compared to its neat (zero interferent) mean result, and recoveries were calculated.

≤ 10 % Change or ≤ 3 mmol/L up to:

	Hemolysis	Lipemia	Bilirubin
Sodium	600 mg/dL	2500 mg/dL	24 mg/dL
Potassium	Do not use hemolyzed serum	2500 mg/dL	24 mg/dL
Chloride	600 mg/dL	2500 mg/dL	24 mg/dL
Glucose	600 mg/dL	700 mg/dL	12 mg/dL

Method Comparisons:

Clinical specimens (n = 69, 69, 69, and 136 for sodium, potassium, chloride, and glucose, respectively), spanning the dynamic ranges, were assayed in singleton and in a blinded fashion by the Pictus 700 (y-axis) and the predicate system. The specimens were previously-collected



serum samples that had been stored frozen and then thawed prior to analysis. Deming regression analysis data appear below.

Sodium	Result		Potassium	Result
N	69		N	69
Correlation Coefficient (r)	0.995		Correlation Coefficient (r)	0.998
Slope (95% CIs)	1.002 (0.978 to 1.027)		Slope (95% CIs)	0.999 (0.984-1.014)
Intercept	-1.02 (-4.7 to 2.2)		Intercept	0.02 (-0.05 to 0.09)

CI = confidence intervals

Chloride	Result		Glucose	Result
N	69		N	136
Correlation Coefficient (r)	0.997		Correlation Coefficient (r)	0.999
Slope (95% CIs)	1.015 (0.996 to 1.035)		Slope (95% CIs)	0.993 (0.987 to 1.000)
Intercept	-1.90 (-3.9 to 0.1)		Intercept	1.2 (-0.1 to 2.4)

807.92 (b)(2): Brief Description of Clinical Data

Not applicable

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

The Diatron Pictus 700 Clinical Chemistry Analyzer is substantially equivalent to the Pictus 400 system, (K101741), and is safe and effective for the claimed intended use.