MAR 2 5 2014 K131703

510(k) Summary

510(K) Owner: Nova Biomedical Corporation
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Date Prepared: **21 March 2014**

Proprietary Name: Stat Profile® Prime CCS Analyzer System, Stat Profile Prime Auto QC Cartridge CCS, Stat Profile Prime Ampuled Control ABG/CCS, Stat Profile Prime Calibrator Cartridge CCS/CCS Comp and Linearity Standard Set A

Common or Usual Name: Blood Gas/Electrolyte/Metabolite/CO-Oximetry Analyzer

Classification Name: Multiple

Classification Names:	**Class No.**	**Reg. No.**	**Class**
Blood Gases and Blood pH system	75CHL	862.1120	II
Sodium Test System	75JGS	862.1665	II
Potassium Test System	75CEM	862.1600	II
Calcium Test System	75JFP	862.1145	II
Chloride Test System	75CGZ	862.1170	II
Glucose Test System	75CGA	862.1345	II
Instrument, Hematocrit, Automated	81GKF	864.5600	II
Calibrators	75JIX	862.1150	II
Quality Control Materials	75JJS	862.1660	I

Product Codes: CHL, JGS, CEM, JFP, CGZ, CGA, GKF, JIX, JJS

Predicate Device: K110648 - Nova Stat Profile pHOx Ultra Analyzer System (including controls, calibrators and Linearity Standards)

Device Description:

The Stat Profile Prime CCS Analyzer is a small, low cost blood gas, metabolite and electrolyte analyzer for laboratory use. The sensors and flow path have been integrated into one replaceable microsensor card, which is replaced periodically according to usage. The product, consumables, installation instructions and packaging are designed for easy customer installation.

Whole blood specimens are aspirated into the analyzer's microsensor card from syringes, tubes, or capillary blood collection devices using a peristaltic pump and a sampling probe. The disposable microsensor card contains the analytical flowpath and all of the measurement sensors (pH, PCO_2, PO_2, Hct, Na^+, K^+, Cl^-, iCa, and Glu (Glucose). Once the analysis measurement is complete, the whole blood specimen is automatically flushed out of the microsensor card flowpath and into a self contained waste collection bag contained within the disposable calibrator cartridge.

The Stat Profile Prime CCS Analyzer will have an enhanced test menu and multiple quality control options. Both traditional Internal and External liquid QC shall be offered, as well as an on-board Quality Management System (QMS), an electronic monitoring approach that insures the analyzer is working properly.

As with the predicate, the Stat Profile Prime CCS Analyzer is microprocessor-based and incorporates:

- traditional sensor technology to measure blood pO_2
- ion selective electrode technology to measure pH, pCO_2, blood sodium, potassium, chloride, and ionized calcium
- enzyme/Amperometric technology for glucose measurements

Liquid quality control materials are available as internal auto-cartridge quality control packs and as external ampules. The sampling, calibration and quality control functions are fully automated.

Internal Calibration standards with dissolved gases are provided in sealed pouches eliminating the need for users to calibrate the blood gas electrodes using external compressed gas cylinders. The Calibration Cartridges contain aqueous solutions within individual flexible bags housed in a cardboard box and a flexible waste bag. Each bag includes a fitment with a septa that is pierced during the insertion of the cartridge into the analyzer. The Calibration Cartridge aqueous solutions allow for 2 point calibration of each parameter as follows:

- Calibrator A - pH, PCO_2, Na, K, Cl, iCa, and Glu (Volume > 500 mL)
- Calibrator B - pH, PO_2, Na, K, Cl, iCa, and Glu (Volume > 250 mL)
- Calibrator F - PCO_2, PO_2 (Volume > 720 mL)
- Reference Solution - KCl (Volume > 300 mL)

The external glass ampule controls contain a buffered bicarbonate solution with a known pH and known levels of Na, K, Cl, iCa, and Glu. The solutions are equilibrated with known levels of O2, CO2, and N2. Each ampule contains 1.7 ml volume.

The internal auto QC cartridge consists of 3 flexible bags within a cardboard carton. Each bag contains an aqueous quality control material for monitoring the measurement of pH, PCO2, PO2, hematocrit (Hct) Na, K, Cl, iCa, and Glucose (Glu). The aqueous quality control materials are composed of a buffered bicarbonate solution, each with a known pH and known level of Na, K, Cl, iCa, and Glu. Solutions are equilibrated with known levels of O2, CO2, and N2. Each bag contains a minimum volume of 100 mL. The aqueous quality control materials are formulated at three levels:

- Control 1: Acidosis, with High Electrolyte, Low Normal Glu
- Control 2: Normal pH, Low-Normal Hct, Normal Electrolyte, High Glu
- Control 3: Alkalosis, High Hct, Low Electrolyte, High Abnormal Glu,

Linearity Standard Set A consists of ampuled buffered solutions containing Ca++, Glu, K+, and Cl-. Each ampule contains 1.8 ml volume.

The Stat Profile Analyzer accepts Lithium heparin whole blood sample from syringes, open tubes, small cups, and capillary tubes. The minimum sample size for both syringe and capillary samples analysis is 100 µL.

Measured Parameters:

The Stat Profile Prime CCS Analyzer measures pH, *P*CO2, *P*O2, Hct, Na+, K+, Cl-, iCa, and Glu (Note: Glucose is optional).

Calculated Parameters:

- pH, PCO_2, PO_2 (corrected to patient temperature)
- Bicarbonate level (HCO_3-)
- Total Carbon Dioxide (TCO_2)
- Base Excess of the blood (BE-b)
- Base Excess of extracellular fluid (BE-ecf)
- Standard Bicarbonate Concentration (SBC)
- Oxygen Content (O_2Ct)
- Oxygen Capacity (O_2Cap)
- Alveolar Oxygen (A)
- Arterial Alveolar Oxygen Tension Gradient ($AaDO_2$)
- Arterial Alveolar Oxygen Tension Ratio (a/A)
- Respiratory Index (RI)
- P50
- PO_2/FIO_2 ratio
- Oxygen Saturation (SO_2%)
- Hemoglobin
- Anion Gap
- Normalized Calcium, nCa

Intended Use:

The Stat Profile Prime CCS Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of pH, PCO2, PO2, Hct, Na+, K+, Cl-, iCa, and Glu (Glucose), in heparinized whole blood.

*P*CO2, *P*O2, pH	Whole blood measurement of certain gases in whole blood, or pH of whole blood, is used in the diagnosis and treatment of life-threatening acid-base disturbances.
Hct	Whole blood measurements of the packed red cell volume of a blood sample are used to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).
Na+	Sodium measurement is used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.
K+	Potassium Measurement is used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.
Cl-	Chloride measurement is used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
iCa	Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
Glu	Glucose measurement is used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Stat Profile Prime Auto QC Cartridge CCS is a quality control material intended for *in vitro* diagnostic use by healthcare professionals for monitoring the performance of the Stat Profile Prime CCS Analyzer.

Stat Profile Prime Ampuled Control ABG/CCS is a quality control material intended for *in vitro* diagnostic use by healthcare professionals for monitoring the performance of Stat Profile Prime CCS Analyzer.

Stat Profile Prime Calibrator Cartridge CCS is intended for the calibration of pH, PCO_2, PO_2, Hct, Na^+, K^+, Cl^-, iCa, and Glucose, using the Stat Profile Prime CCS Analyzer.

Linearity Standard Set A is intended for in vitro diagnostic use with Stat Profile Prime CCS Analyzers to verify calibration, analytical linearity, estimate test imprecision, and detect systematic analytical deviations that may arise from calibrator cartridge or analytical instrument variation.

Summary of the Technological Characteristics:

The Stat Profile Prime CCS Analyzer is substantially equivalent to the previously cleared for market Nova Stat Profile pHOx Ultra Analyzer System in intended use. It uses the same sensor technology and measurement algorithms, and the formulations of the internal and external controls and the calibration cartridge are the same for the tested parameters. The Linearity Standard Set A for use with the Stat Profile Prime CCS Analyzer is identical to those cleared for use with the predicate Nova Stat Profile pHOx Ultra Analyzer System.

Table 1: Comparison of Predicate and Proposed devices

Characteristic	**Predicate: K110648 Stat Profile pHOx Ultra Analyzer**	**Proposed: Stat Profile Prime CCS Analyzer**
Indication For Use	The STP pHOx Ultra Analyzer without CO-Oximeter is intended for *in vitro* diagnostic use by health care professionals and/or point-of-care usage in the quantitative determination of pH, PCO_2, PO_2, SO_2%, Hematocrit (Hct), Hemoglobin (Hb) in heparinized whole blood; Na^+, K^+, Cl^-, Ca^{++}, Mg^{++}, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in heparinized whole blood, serum, or plasma.	The Stat Profile Prime CCS Analyzer System is intended for *in vitro* diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of pH, PCO2, PO2, Hct, Na+, K+, Cl-, iCa, and Glu (Glucose), in heparinized whole blood. *P*CO2, *P*O2, pH: Whole blood measurement of blood gases is used in the diagnosis and treatment of life-threatening acid-base disturbances in critically ill patients with numerous metabolic and pulmonary diseases. Hct: Whole blood measurements of hematocrit are used to estimate that red blood cells are present in sufficient quantity to carry oxygen and carbon dioxide. Na+: Sodium measurement is used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance. K+: Potassium Measurement is used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high potassium levels. Cl-: Chloride measurement is used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis. iCa: Ionized Calcium measurement is used in the diagnosis and treatment of hypertension, renal disease, and vitamin D related disorders. Also useful in the diagnosis and treatment of patients with increased total protein and/or albumin levels, as in dehydration. Glu: Glucose measurement is used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.
Acceptable Samples	Sodium or lithium heparinized whole	Lithium heparinized whole blood from syringes, open tubes, small cups, and

Characteristic	Predicate: K110648 Stat Profile pHOx Ultra Analyzer	Proposed: Stat Profile Prime CCS Analyzer
	blood, serum, or plasma samples from syringes, open tubes, small cups, and capillary tubes.	capillary tubes.
Sample Volumes	100µL (syringe and capillary)	100µL (syringe and capillary)
Measurement Range		
pH	6.500-8.000	Same
PCO_2	3.0 -200 mmHg	Same
PO_2	0-800 mmHg	5-765 mmHg
Hct	12%-70%	Same
Na^+	80-200 mmol/L	Same
K^+	1.0-20.0 mmol/L	Same
Cl^-	50-200 mmol/L	Same
iCa (Ca^{++})	0.10-2.70 mmol/L	0.20-2.70 mmol/L
Glu	15-500 mg/dL	Same
Principles of Measurement		
pH	Hydrogen ion-selective sensor	Same
PCO_2	Severinghaus-type sensor	Same
PO_2	Polarographic Clark-type sensor	Same
Hct	Impedance sensor	Same
Na^+	Sodium ion-selective sensor	Same
K^+	Potassium ion-selective sensor	Same
Cl^-	Chloride ion-selective sensor	Same
iCa (Ca^{++})	Calcium ion-selective sensor	Same

Characteristic	Predicate: K110648 Stat Profile pHOx Ultra Analyzer	Proposed: Stat Profile Prime CCS Analyzer
Glu	Glucose Oxidase Enzymatic sensor	Same
Touch Screen	12.1" LCD, 1024x768 pixel, Resistive Touch	5.7" VGA full color display with LED backlight and integrated touch panel
Menu	Fully configurable test menu based on above sensors	Same
Bar Code Scanner	External (optional) 1D	Internal Integrated 1D/2D
Printer	2" Roll, Thermal Transfer	Same
Pump	Peristaltic Pump w/ Pressure Plate, TPE Tubing (Pharmed BPT)	Same
Analog Board	Precision low level analog front end w/ amperometric and potentiometric amplifiers, air detector circuitry and temperature control circuitry	Same

Characteristic	Predicate: K110648 Stat Profile pHOx Ultra Calibrator Cartridge	Proposed: Stat Profile Prime Calibrator Cartridge CCS
Indication For Use	The intended use of the Nova STP pHOx Ultra Calibrator Cartridge is for the quantitative determination of pH, PCO2, PO2, SO2%, Hematocrit (Hct), Hemoglobin (Hb) in heparinized whole blood; Na+, K+, Cl-, Ca++, Mg++, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in heparinized whole blood, serum, or plasma.	The Stat Profile Prime Calibrator Cartridge CCS is intended for the calibration of pH, PCO_2, PO_2, Hct, Na^+, K^+, Cl^-, iCa, and Glucose using the Stat Profile Prime CCS Analyzer.
Configuration	2 level calibration standards per analyte, and reference solution	Same
Packaging	Liquid in Mylar bags inside cardboard container. Includes a waste collection bag. Self-contained, disposable packaging.	Same

Characteristic	Predicate: K110648 Stat Profile pHOx Ultra/CCX ABG and CO-Oximeter Controls	Proposed: Stat Profile Prime Auto QC Cartridge CCS

Indication For Use	Nova STP pHOx Ultra/CCX ABG and CO-Oximeter Controls and Autocartridge QC are intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of Nova STP pHOx Ultra/CCX Analyzers.	The Stat Profile Prime Auto QC Cartridge CCS is a quality control material intended for *in vitro* diagnostic use by healthcare professionals for monitoring the performance of the Stat Profile Prime CCS Analyzer.
Configuration	3 level aqueous electrolyte, metabolite and gas solutions.	Same
Packaging	Cartridge: Solution in Mylar bags inside cardboard container. Includes a waste collection bag. Self-contained, disposable packaging.	Same

Characteristic	**Predicate: K110648 Stat Profile pHOx Ultra/CCX ABG and CO-Oximeter Controls**	**Proposed: Stat Profile Prime Ampuled Control ABG/CCS**
Indication For Use	Nova STP pHOx Ultra/CCX ABG and CO-Oximeter Controls and Autocartridge QC are intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of Nova STP pHOx Ultra/CCX Analyzers.	The Stat Profile Prime Ampuled Control ABG/CCS is a quality control material intended for *in vitro* diagnostic use by healthcare professionals for monitoring the performance of Stat Profile Prime CCS Analyzer.
Configuration	3 level aqueous electrolyte, metabolite and gas solutions.	Same
Packaging	Ampules: Each glass ampule contains 1.7 ml volume.	Same

Characteristic	**Predicate: K110648 Stat Profile pHOx Ultra Linearity Standards**	**Proposed: Linearity Standard Set A**
Indication For Use	For in vitro diagnostic use with NOVA, Stat Profile/Ultra, Stat Profile pHOx Plus/L/C/M, Stat Profile pHOx Ultra, Stat Profile Prime CCS, and Stat Profile CCX Analyzers to verify calibration, analytical linearity, estimate test imprecision, and detect systematic analytical deviations that may arise from calibrator cartridge or analytical instrument variation.	The Linearity Standard Set A is intended for in vitro diagnostic use with Stat Profile Prime CCS Analyzers to verify calibration, analytical linearity, estimate test imprecision, and detect systematic analytical deviations that may arise from calibrator cartridge or analytical instrument variation.
Configuration	4 level aqueous solutions in glass ampules. Contain electrolyte, metabolite and gas solutions.	Same
Packaging	Ampules: Each glass ampule contains 1.8 ml volume	Same

Summary of Performance Testing:

Bench testing was completed to demonstrate that the Stat Profile Prime CCS Analyzer is substantially equivalent in performance, safety and efficacy to the Stat Profile pHOx Ultra Analyzer System.

The bench testing included:

- Method Comparison Studies
- Precision/Reproducibility Studies
- Run to Run Precision
- Within Run Precision
- Linearity Testing
- Specificity / Interference Testing
- Detection Limit

The results of the testing confirmed that the performance of the Stat Profile Prime CCS Analyzer System is substantially equivalent to that of the Nova Stat Profile pHOx Ultra Analyzer System (predicate device).

Conclusion:

The results of software validation and performance verification testing confirmed that the Stat Profile Prime CCS Analyzer is safe and effective for its intended purpose and that the Stat Profile Prime CCS Analyzer System is substantially equivalent to that of the Nova Stat Profile pHOx Ultra Analyzer System K110648 (predicate device).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2014

NOVA BIOMEDICAL CORPORATION
PAUL MACDONALD
CHIEF OFFICER, QA & REG. AFFAIRS
200 PROSPECT ST
WALTHAM MA 02454

Re: K131703

Trade/Device Name: Nova Stat Profile Prime CCS Analyzer System, Stat Profile Prime Auto QC Cartridge CCS, Stat Profile Prime Ampuled Control ABG/CCS, Stat Profile Prime Ampuled Control ABG/CCS, Stat Profile Prime Calibrator Cartridge CCS/CCS Comp, Nova Linearity Standard Set A
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: II
Product Code: CHL, JGS, CEM, JFP, CGZ, CGA, GKF, JIX, JJS
Dated: February 19, 2014
Received: February 20, 2014

Dear Mr. MacDonald:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Courtney H. Lias -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K131703

Device Name

Stat Profile® Prime CCS Analyzer System, Stat Profile Prime Auto QC Cartridge CCS, Stat Profile Prime Ampuled Control ABG/CCS, Stat Profile Prime Calibrator Cartridge CCS/CCS Comp and Linearity Standard Set A

Indications for Use *(Describe)*

The Stat Profile Prime CCS Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of pH, PCO2, PO2, Hct, Na+, K+, Cl-, iCa, and Glu (Glucose), in heparinized whole blood.

PCO2, PO2, pH: Whole blood measurement of certain gases in whole blood, or pH of whole blood, is used in the diagnosis and treatment of life-threatening acid-base disturbances.

Hct: Whole blood measurements of the packed red cell volume of a blood sample are used to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).

Na+: Sodium measurement is used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.

K+: Potassium Measurement is used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.

Cl-: Chloride measurement is used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

iCa: Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Glu: Glucose measurement is used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

The Stat Profile Prime Auto QC Cartridge CCS is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of the Stat Profile Prime CCS Analyzer.

The Stat Profile Prime Ampuled Control ABG/CCS is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of Stat Profile Prime CCS Analyzer.

510(k) Number *(if known)*

K131703

Device Name

Stat Profile® Prime CCS Analyzer System, Stat Profile Prime Auto QC Cartridge CCS, Stat Profile Prime Ampuled Control ABG/CCS, Stat Profile Prime Calibrator Cartridge CCS/CCS Comp and Linearity Standard Set A

The Stat Profile Prime Calibrator Cartridge CCS is intended for the calibration of pH, PCO2, PO2, Hct, Na+, K+, Cl-, iCa, and Glucose using the Stat Profile Prime CCS Analyzer.

Linearity Standard Set A is intended for in vitro diagnostic use with Stat Profile Prime CCS Analyzers to verify calibration, analytical linearity, estimate test imprecision, and detect systematic analytical deviations that may arise from calibrator cartridge or analytical instrument variation.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

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