April 14, 2020

Nova Biomedical Corporation
Rachel Gilbert
Regulatory Affairs Specialist II
200 Prospect Street
Waltham, MA 02454

Re: K200403
    Trade/Device Name: Stat Profile® Prime Plus Analyzer System
    Regulation Number: 21 CFR 862.1665
    Regulation Name: Sodium test system
    Regulatory Class: Class II
    Product Code: JGS, CEM, CGZ, JFP, CFA
    Dated: February 12, 2020
    Received: February 19, 2020

Dear Rachel Gilbert:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

                              Sincerely,

                              Marianela Perez-Torres, Ph.D.
                              Acting Deputy Director
                              Division of Chemistry
                                 and Toxicology Devices
                              OHT7: Office of In Vitro Diagnostics
                                 and Radiological Health
                              Office of Product Evaluation and Quality
                              Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number *(if known)*
k200403

Device Name
Stat Profile® Prime Plus Analyzer System

Indications for Use *(Describe)*
The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of Sodium, Potassium, Chloride, Ionized Calcium, and Ionized Magnesium in heparinized arterial and venous whole blood.

Sodium (Na)	Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.
Potassium (K)	Potassium measurements are used in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.
Chloride (Cl)	Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
Ionized Calcium (iCa)	Ionized 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)
Ionized Magnesium (iMg)	Ionized magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low levels of magnesium) and hypermagnesemia (abnormally high levels of magnesium).

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.

510(k) Summary
k200403

510(K) Owner: Nova Biomedical Corporation
Registration Number: 1219029
Address: 200 Prospect St.
                      Waltham, MA 02454
Phone: 781-894-0800
Fax Number: 784-891-4806
Contact Person: Rachel Gilbert, Regulatory Affairs Specialist II
Date Prepared: February 12, 2020

Proprietary Name: Stat Profile® Prime Plus Analyzer System

Common or Usual Name: Blood Analyzer

Classification Name: Multiple

Regulation Section	Classification	Product Code
21 CFR § 862.1665 Sodium Test System	Class II	JGS
21 CFR § 862.1600 Potassium Test System	Class II	CEM
21 CFR § 862.1170 Chloride Test System	Class II	CGZ
21 CFR § 862.1145 Calcium Test System	Class II	JFP
21 CFR § 862.1495 Magnesium Test System	Class I, reserved	CFA

Product Code:
JGS

Predicate Device:
k180428 – Stat Profile Prime Plus Analyzer System

Device Description:
The Stat Profile Prime Plus Analyzer System is a low cost, low maintenance analyzer for hospital laboratory and point-of-care settings. It consists of the analyzer, sensor cartridges, and thermal paper for an onboard printer. Optionally, it provides for reading of barcode labels (such as operator badges and data sheets).

The Stat Profile Prime Plus Analyzer has slots to accommodate two sensor cartridges (Primary and Auxiliary). The analyzer will determine the configuration of the system by detecting which sensor cards are installed.

Primary Sensor Card Port:
There are two options for the primary sensor card:
- **Primary Sensor Card 1** shall enable and report the following listed analytes:
  - Sodium, Potassium, Chloride, Calcium, Ionized Magnesium
- **Primary Sensor Card 2** shall enable and report the following listed analytes:
  - Sodium, Potassium, Chloride, Calcium, Ionized Magnesium

As with the predicate, the Stat Profile Prime Plus Analyzer is a blood gas, co-oximetry, electrolyte, chemistry, and hematology analyzer with an enhanced test menu and multiple quality control options. Both traditional internal and external quality control is available, as well as an on-board Quality Management System (QMS), and an electronic monitoring approach that insures the analyzer is working properly at all times.

The Stat Profile Prime Plus Analyzer accepts samples from syringes and open tubes. The minimum sample size for analysis is 135 µL.

Sample collection, preparation and application to the analyzer are the same as for the previously cleared predicate. The end user can select which analytes are to be tested in the panel.

Stat Profile Prime Plus Analyzer System Components:
The Stat Profile Prime Plus Analyzer System is comprised of the following components.
- Stat Profile Prime Plus Analyzer System
- Primary Sensor Cartridge
- Stat Profile Prime Plus Auto-Cartridge Quality Control Pack
- Stat Profile Prime Plus Calibrator Cartridge
- Stat Profile Prime Plus External Ampuled Control
- IFU/Labeling

Sample Types:
The Stat Profile Prime Plus Analyzer System accepts lithium heparinized arterial and venous whole blood.

Measured Parameters:
The Stat Profile Prime Plus Analyzer measures:
- Sodium (Na)
- Potassium (K)
- Chloride (Cl)
- Ionized Calcium (iCa)
- Ionized Magnesium (iMg)

Calculated Parameters:
The Prime Plus Analyzer also provides the following parameter results calculated based on results of the directly measured parameters:
- Anion Gap (Gap)
- Blood Osmolality (OSM)
- nCA to nMg Ratio (nCa/nMg)
- Normalized Calcium (nCa)
- Normalized Magnesium (nMg)

Intended Use:
The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of Sodium, Potassium, Chloride, Ionized Calcium, and Ionized Magnesium in heparinized arterial and venous whole blood.

Indications for Use:

Sodium (Na)	Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.
Potassium (K)	Potassium measurements are used in the diagnosis and treatment of disease conditions characterized by low or high potassium levels.
Chloride (Cl)	Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
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Ionized Magnesium (iMg)	Ionized magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low levels of magnesium) and hypermagnesemia (abnormally high levels of magnesium).

Summary of the Technological Characteristics:

The Stat Profile Prime Plus Analyzer is substantially equivalent to the previously cleared for market Stat Profile Prime Plus Analyzer 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.

Principle of Measurement:
Sodium, Potassium, Chloride, Ionized Calcium, Ionized Magnesium:
The parameters are measured by an Ion-Selective Electrode (ISE) that selectively measures the activity of ionic species. When the ISE is contacted with a sample, potential is developed. The potential is proportional to the logarithm of the ionic activity and is measured versus a reference electrode.

Summary of Performance Testing:

Bench testing was previously completed and summarized in k180428 to show that the Stat Profile Prime Plus Analyzer demonstrates substantial equivalence to the predicate submission.

The bench testing included:
- Method Comparison Studies
- Precision/Reproducibility – Within Run and Run to Run Studies
- Linearity Testing
- Specificity/Interference Testing
- Detection Limit

Summary of Point-of-Care Testing:

A Point-of-Care (POC) study was conducted to show that the Stat Profile Prime Plus Analyzer demonstrates substantial equivalence to the predicate submission. The testing compared results obtained by trained Healthcare Professionals to results obtained by POC personnel on the same specimens using the same analyzer. The Stat Profile Prime Plus Analyzer was evaluated by point-of-care (POC) personnel in 3 POC sites including a Cardiothoracic Intensive Care Unit (CTICU), an Emergency Department (ED) and a Respiratory Therapy Lab (RT). A total of 61 Respiratory Care, 12 Nursing, and 1 Exercise Physiology POC personnel participated from the 3 POC settings over the course of the study. The personnel represent trained, qualified staff found in typical POC sites where blood gas analyzers are utilized. All testing was performed using quality control materials or discarded blood gas specimens.

Method Comparison Studies:

Method Comparison studies on venous and arterial whole blood specimens were conducted using methods described in CLSI "Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition", CLSI EP9-A2. Combined method comparison data from all 3 POC settings is summarized in Table 1.

Table 1: Venous and Aterial Whole Blood Method Comparison Results – Point of Care vs Lab (ED, RT and CTICU)

analyte	N	# altered samples	range	Slope	Intercept	r	MDL	95% Confidence Interval of Bias	
								Lower Limit	Upper Limit
Na	432	18	90.0 - 187.0	0.9964	0.4488	0.9949	**120**	119.8	120.2
								160	159.6	160.1
K	435	21	1.10 - 17.60	1.0158	-0.0678	0.9993	**2.8**	2.77	2.81
								6.0	5.98	6.04
Cl	434	20	56.0 - 173.0	0.9963	0.4416	0.9971	**80**	79.9	80.4
								130	129.8	130.1
iCa	434	20	0.51 - 2.48	0.9820	0.0239	0.9871	**0.80**	0.80	0.82
								1.54	1.53	1.54
iMg	426	13	0.24 - 1.36	1.0020	-0.0021	0.9910	**0.3**	0.29	0.30
								0.8	0.80	0.80

Total Imprecision Performance:

The estimates for total impression were obtained from different POC personnel running 3 levels of Stat Profile Prime Plus Quality Control/Linearity Materials in duplicate each day for a total of 20 runs on 3 Stat Profile Prime Plus analyzers. The protocol was based upon methods described in CLSI Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition, CLSI EP5-A2T. The total imprecision data from one representative POC site is shown in Table 2 is representative of the expected total imprecision performance obtainable by POC personnel using the Stat Profile Prime Plus analyzer using external quality control and linearity materials.

Table 2: Total Imprecision From ED Site

	Mean	Within Run SD	Within Run %CV	Total SD	Total %CV
Total Imprecision Data-Level 4					
Na (mmol/L)	136.2	0.8	0.6	0.9	0.6
K (mmol/L)	3.88	0.05	1.4	0.08	2.2
Cl (mmol/L)	123.2	0.6	0.5	0.7	0.6
Ca (mmol/L)	1.07	0.02	1.7	0.02	2.1
Mg (mmol/L)	0.60	0.02	3.6	0.03	4.4
Total Imprecision Data-Level 5					
Na (mmol/L)	109.8	1.0	0.9	0.9	0.8
K (mmol/L)	6.24	0.06	1.0	0.12	1.9
Cl (mmol/L)	95.1	0.4	0.4	0.6	0.6
Ca (mmol/L)	1.56	0.04	2.8	0.04	2.7
Mg (mmol/L)	1.07	0.03	2.7	0.07	6.5

	Mean	Within Run SD	Within Run %CV	Total SD	Total %CV
Total Imprecision Data-Linearity Level 4					
Na (mmol/L)	168.6	1.5	0.9	2.0	1.2
K (mmol/L)	11.64	0.12	1.0	0.18	1.5
Cl (mmol/L)	132.7	1.0	0.8	1.2	0.9
Ca (mmol/L)	0.48	0.01	1.6	0.01	1.9
Mg (mmol/L)	0.24	0.01	2.3	0.01	5.4

Within-Run Whole Blood Precision:

Whole blood with-run precision of the Stat Profile Prime Plus Analyzer System in the hands of point-of-care operators was assessed by a minimum of two (2) point-of-care operators at each of the three (3) POC sites for a total of nine (9) operators across the 3 testing locations. Each precision run consisted of ten (10) replicate measurements using both fresh, native and altered whole blood samples. A total of five (5) different native samples and two (2) altered samples were evaluated at each site. Each whole blood specimen was maintained in a syringe. The POC operator performed all sample analysis steps including sample analysis, removal of resultant air bubble(s) from the syringe, recapping of the syringe and mixing prior to the next sample analysis. The whole blood within-run precision data from one representative POC site is shown in Table 3 and is representative of the expected within-run precision obtainable by POC personnel using the Stat Profile Prime Plus analyzer using whole blood samples.

Table 3: Within Run Precision with Whole Blood Samples (n=10) – ED

	Mean	SD	%CV	95% CI
Sample 1				
Na (mmol/L)	123.7	0.82	0.67	122 - 125
K (mmol/L)	4.71	0.03	0.67	4.6 - 4.8
Cl (mmol/L)	88.6	0.52	0.58	88 - 90
Ca (mmol/L)	1.24	0.01	0.43	1.22 - 1.25
Mg (mmol/L)	0.56	0.01	1.50	0.55 - 0.58
Sample 2				
Na (mmol/L)	138.2	0.42	0.31	137 - 139
K (mmol/L)	1.94	0.05	2.66	1.8 - 2.0
Cl (mmol/L)	116.8	0.63	0.54	116 - 118
Ca (mmol/L)	0.75	0.01	1.13	0.73 - 0.76
Mg (mmol/L)	0.31	0.01	2.63	0.30 - 0.33
Sample 3				
Na (mmol/L)	141.1	0.32	0.22	140 - 142
K (mmol/L)	4.02	0.04	1.05	3.9 - 4.1
Cl (mmol/L)	103.8	0.42	0.41	103 - 105
Ca (mmol/L)	1.28	0.01	0.40	1.27 - 1.29
Mg (mmol/L)	0.61	0.00	0.52	0.60 - 0.62
Sample 4				
Na (mmol/L)	142.9	0.57	0.40	142 - 144
K (mmol/L)	4.11	0.03	0.77	4.0 - 4.2
Cl (mmol/L)	103.0	0.00	0.00	103 - 103
Ca (mmol/L)	1.31	0.01	0.54	1.29 - 1.32
Mg (mmol/L)	0.62	0.01	1.02	0.61 - 0.63

	Mean	SD	%CV	95% CI
Sample 5				
Na (mmol/L)	137.9	0.32	0.23	137 - 139
K (mmol/L)	3.30	0.00	0.00	3.3 - 3.3
Cl (mmol/L)	109.1	0.32	0.29	108 - 110
Ca (mmol/L)	0.98	0.01	0.52	0.97 - 0.99
Mg (mmol/L)	0.46	0.00	0.91	0.45 - 0.47
Sample 6 (Altered)				
Na (mmol/L)	133.6	0.70	0.52	132 - 135
K (mmol/L)	3.73	0.05	1.30	3.6 - 3.8
Cl (mmol/L)	104.4	0.70	0.67	103 - 106
Ca (mmol/L)	1.13	0.01	0.95	1.11 - 1.16
Mg (mmol/L)	0.48	0.01	2.29	0.46 - 0.50
Sample 7 (Altered)				
Na (mmol/L)	138.3	0.67	0.49	137 - 140
K (mmol/L)	7.91	0.09	1.11	7.7 - 8.1
Cl (mmol/L)	109.6	0.52	0.47	109 - 111
Ca (mmol/L)	1.22	0.01	0.61	1.20 - 1.23
Mg (mmol/L)	0.58	0.01	0.98	0.57 - 0.59

Conclusion:
The results of the POC clinical performance verification testing confirmed that the Stat Profile Prime Plus Analyzer is substantially equivalent to the predicate Stat Profile Prime Plus Analyzer System (k180428).

Table 4: Comparison of Predicate and Proposed Devices

Characteristic	Predicate:	Proposed:
Indication For Use	The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings for quantitative determination of sodium, potassium, chloride, ionized calcium, and ionized magnesium in heparinized arterial and venous whole blood.	The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of care usage for quantitative determination of sodium, potassium, chloride, ionized calcium, and ionized magnesium in heparinized arterial and venous whole blood.
Acceptable Samples		
Sample Types	Lithium heparin whole blood from syringes and open tubes	Same
Sample Volumes	135µL	Same
Measurement Range		
Sodium	80-200 mmol/L	Same
Potassium	1.0-20.0 mmol/L	Same
Chloride	50-200 mmol/L	Same
Ionized Calcium	0.4-10.8 mg/dL	Same
Ionized Magnesium	0.24-3.65 mg/dL	Same
Principles of Measurement		
Sodium	Ion-Selective Electrode	Same
Potassium	Ion-Selective Electrode	Same
Chloride	Ion-Selective Electrode	Same
Ionized Calcium	Ion-Selective Electrode	Same
Ionized Magnesium	Ion-Selective Electrode	Same
Touch Screen	10.1" WXGA 1280 x 800 color touch screen	Same
Menu	Fully configurable test menu based on available sensors	Same
Bar Code Scanner	Internal Integrated 1D/2D	Same
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