July 19, 2019

Nova Biomedical Corporation
Cesidio Tempesta
Regulatory Affairs Manager
200 Prospect St.
Waltham, MA 02454

Re: K191365
Trade/Device Name: Stat Profile Prime ES Comp Plus Analyzer System
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium test system
Regulatory Class: Class II
Product Code: JGS, CEM, CGZ, JJE
Dated: May 20, 2019
Received: May 22, 2019

Dear Cesidio Tempesta:

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,

Kellie B. Kelm, Ph.D.
Acting 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: *0613012020*
See *PRA Statement below.*

51O(k) Number K191365

Device Name
Stat Profile Prime ES Comp Plus Analyzer System

Indications for Use *(Describe)*

The Stat Profile Prime ES Comp Plus Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of Sodium, Potassium, and Chloride in heparinized venous whole blood, plasma and serum.

Sodium (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.

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

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

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
K191365

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: Cesidio Tempesta, Regulatory Affairs Manager
Date Prepared: 18 July, 2019

Proprietary Name: Stat Profile Prime ES Comp Plus Analyzer System

Common or Usual Name: Blood Gas/Electrolyte Analyzer

Classification Name: Multiple

Classification Names:	Reg. No.	Class	Product Code	Panel
Sodium Test System	862.1665	II	JGS	Chemistry (75)
Potassium Test System	862.1600	II	CEM	
Chloride Test System	862.1170	II	CGZ	
Analyzer, chemistry (photometric, discrete), for clinical use	862.2160	I	JJE	

Product Codes: JGS, CEM, CGZ

Predicate Devices:

K110648 - Nova Stat Profile pHOx Ultra Blood Gas Analyzer

Device Description:

The Stat Profile Prime ES Comp Plus Analyzer is a small, low cost blood electrolyte analyzer. 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 ES Comp Plus Analyzer has an enhanced test menu and multiple quality control options. External Control Solutions (ampules) shall be offered, as well as an on-board Quality Management System (QMS), an electronic monitoring approach that insures the analyzer is working properly.

The Stat Profile Prime ES Comp Plus Analyzer can accommodate either of two sensor cards in the sensor card housing. The analyzer will determine the test configuration of the system by detecting which sensor card is installed.

The two options for the sensor card are:

- Sensor Card 1 (Basic Electrolyte Panel plus Hct) shall enable and report the following listed analytes: Hct, Na, K, Cl
- Sensor Card 2(Full Electrolyte Panel plus pH & Hct) shall enable and report the following listed analytes: pH, Hct, Na, K, Cl, iCa, iMg

As with the predicates, the Stat Profile Prime ES Comp Plus Analyzer is microprocessor-based and incorporates ion selective electrode technology to measure sodium, potassium, and chloride.

The Prime ES Comp Plus can be configured with an optional sample tray, which allows the user to run up to 10 consecutive samples. Tray samples may be any combination of Serum/Plasma or control solutions. Whole Blood samples may only be run in STAT Mode (not tray mode).

Calibration standards are provided in sealed pouches within a calibrator pack. Liquid quality control materials are available as external ampules. Sampling and calibration are fully automated.

The Stat Profile Prime ES Comp Plus Analyzer accepts lithium heparinized whole blood sample from syringes, open tubes, and small cups. The minimum sample sizes for analysis is 100 µL.

Measured Parameters:

The Stat Profile Prime ES Comp Plus Analyzer measures Na+, K+, and Cl-.

Intended Use:

The Stat Profile Prime ES Comp Plus Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of Sodium, Potassium, and Chloride in heparinized venous whole blood, plasma and serum.

Indication for Use:

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

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

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

Summary of the Technological Characteristics:

The Stat Profile Prime ES Comp Plus Analyzer is substantially equivalent to the previously cleared for market Nova Stat Profile pHOx Ultra Blood Gas Analyzer System in intended use. It uses the same sensor technology and measurement algorithms, and the formulations of the external controls and the calibration cartridge are the same for the tested parameters. The linearity standards and External Control solutions for use with the Stat Profile Prime ES Comp Plus Analyzer are substantially equivalent to those cleared for use with the predicate Nova Stat Profile pHOx Ultra Blood Gas Analyzer System (K110648).

Table Error! No text of specified style in document.**-1: Comparison of Predicate and Proposed devices**

Characteristic	Predicate Stat Profile pHOx Ultra Blood Gas Analyzer (K110648)	Proposed Stat Profile Prime ES Comp Plus 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 ES Comp Plus Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of pH, Hematocrit, Sodium, Potassium, Chloride, Calcium and Magnesium in heparinized venous whole blood, and pH, Sodium, Potassium, Chloride, Calcium and Magnesium in plasma and serum.
Acceptable Samples	Sodium or lithium heparinized whole blood, serum, or plasma samples from syringes, open tubes, small cups, and capillary tubes can be used on the STP pHOx Ultra Analyzer.	Lithium heparin whole blood, serum and plasma samples from syringes, open tubes, and small cups
Sample Volumes	60-210µL dependent on selected test panel	100µL
Measurement Range		
Na^+	80 - 200 mmol/L	Same
K^+	1.0 - 20.0 mmol/L	Same
Cl^-	50 - 200 mmol/L	Same
Principles of Measurement		
Na^+	Sodium ion-selective glass sensor	Same
K^+	Potassium ion-selective sensor	Same
Cl^-	Chloride ion-selective 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

Summary of Performance Testing:

Performance testing was completed to demonstrate that the Stat Profile Prime ES Comp Plus Analyzer is substantially equivalent in performance, safety and efficacy to the predicate Nova Stat Profile pHOx Ultra Blood Gas Analyzer (K110648).

The performance testing included:

- Method Comparison Studies
- Precision/Reproducibility Studies
- Run to Run Precision
- Linearity Testing
- Specificity / Interference Testing
- Detection Limit
- Shelf Life Stability Testing

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

Conclusion:

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