September 26, 2018

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

Re: K180340
Trade/Device Name: Stat Profile Prime Plus Analyzer System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, CDS, CGL
Dated: August 24, 2018
Received: August 27, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement on last page

510(k) Number K180340

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 for quantitative determination of Glucose, Creatinine, and Blood Urea Nitrogen, in heparinized arterial and venous whole blood.

Glucose (Glu)	Measurements are used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell tumor.
Creatinine (Creat)	Measurements are used in the diagnosis and treatment of certain renal conditions and for monitoring adequacy of dialysis.
Blood Urea Nitrogen (BUN)	Measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

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
K180340

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 Specialist

Date Prepared: September 25, 2018

Proprietary Name: Stat Profile Prime Plus Analyzer System

Common or Usual Name: Blood Gas Analyzer

Classification Name: Multiple

Classification Name	Regulation #	Class	Product Code
Glucose test system	862.1345	II	CGA
Creatinine test system	862.1225	II	CGL
Urea Nitrogen Test System	862.1770	II	CDS

Product Code: CGA

Predicate Device:

K110648 - Stat Profile pHOx Ultra Analyzer System

Device Description:

The Stat Profile Prime Plus Analyzer System is designed to be a low cost, low maintenance analyzer for the hospital laboratory setting. 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 system architecture and user interface for this proposed device is based on the previously cleared Stat Profile Prime CCS Analyzer System (K131703). The primary predicate for this proposed device is the Stat Profile pHOx Ultra Analyzer System (K110648).

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. The reporting of CO-Oximeter parameters (or not reporting them) will also be determined by the selection of the Sensor Cards:

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:
  - PO_2, PCO_2, pH, Hct, tHb, Na, Cl, K, iCa, iMg, Glu, SO2, O2Hb, COHb, MetHb, HHb
- **Primary Sensor Card 2** shall enable and report the following listed analytes:
  - PO2, PCO2, pH, Hct, tHb, Na, Cl, K, iCa, iMg, Glu, SO2

Auxiliary Sensor Card Port:

The reporting of Creatinine and BUN parameters (Or not reporting them) shall be determined by the selection of the Auxiliary Sensor Card

- **Auxiliary Sensor Card 1** enables Creatinine and BUN parameters
- **Auxiliary Sensor Card 2** is a "dummy" sensor card, and will not report any parameters.

Similar to the primary predicate device, 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 will be used, as well as an on-board Quality Management System (QMS), an electronic monitoring approach that insures the analyzer is working properly at all times.

The Stat Profile Prime Plus Analyzer accepts samples from syringes, open tubes, and small cups. 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
- Auxiliary 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:

- Glucose (Glu)
- Creatinine (Creat)
- Blood Urea Nitrogen (BUN)

Calculated Parameters:

The following parameters are calculated by the Prime Plus Analyzer based on results of the directly measured parameters.

- BUN/Creat Ratio (BUN/Creat)
- Blood Osmolality (OSM)
- Estimated Glomerular Filtration Rate (eGFR)

Intended Use:

The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings for quantitative determination of Glucose, Creatinine, and Blood Urea Nitrogen, in heparinized arterial and venous whole blood.

Glucose (Glu)	Measurements are used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell tumor.
Creatinine (Creat)	Measurements are used in the diagnosis and treatment of certain renal conditions and for monitoring adequacy of dialysis.
Blood Urea Nitrogen (BUN)	Measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

Summary of the Technological Characteristics:

The Stat Profile Prime Plus Analyzer is substantially equivalent to the previously cleared for market Stat Profile pHOx Ultra Analyzer System (K110648) 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 External Control solutions for use with the Stat Profile Prime Plus Analyzer are substantially equivalent to those cleared for use with the predicate Stat Profile pHOx Ultra Analyzer System (K110648). See **Table 1** for comparison of the predicate and proposed devices.

Principles of Measurement:

Glucose:

Glucose measurement is based on the level of H_2O_2 produced during the enzymatic reaction between glucose and oxygen molecules in the presence of the glucose oxidase enzyme.
At a constant potential of 0.70 volts, electroactive H_2O_2 is oxidized at the surface of the platinum anode. The current generated by the flow of electrons at the surface of the platinum electrode is proportional to the glucose concentration of the sample.

Creatinine:

The Prime Plus Creatinine sensor uses 3 enzymes. These 3 enzymes catalyze the conversion of Creatinine, ultimately forming formaldehyde, glycine, and hydrogen peroxide.

At a constant potential of 0.70 volts, electroactive H_2O_2 is oxidized at the surface of the platinum anode. The current generated by the flow of electrons at the surface of the platinum electrode is proportional to the Creatinine concentration of the sample.

BUN:

The Prime Plus Analyzer uses urease, which has been chemically bonded to a membrane, to catalyze the conversion of urea present in the sample to ammonia and CO_2.

At the pH of the sample, ammonia converts predominantly to the ammonium ion. An ammonium ion selective electrode is used to detect the ammonium formed by the above reactions. This measurement is then related to the concentration of urea present in the original sample via the Nernst equation.

Summary of Performance Testing:

Performance testing was completed to demonstrate that the Stat Profile Prime Plus Analyzer is substantially equivalent in performance, safety and efficacy to the Stat Profile pHOx Ultra Analyzer System. The performance testing included:

Method Comparison Studies:

A study was performed to compare the Stat Profile Prime Plus to the Nova Stat Profile pHOx Ultra analyzer to assess the equivalence of the analyzers in the measurement of Glucose, Creatinine, and BUN in heparinized whole blood in a clinical laboratory setting.

The blood comparison data for Glucose, Creatinine, and BUN, for the Stat Profile Prime Plus analyzers meet the acceptance criteria.

Precision/Reproducibility - Within Run and Run to Run Studies:

Within Run and Run to Run precision was evaluated by replication studies performed on three Stat Profile Prime Plus analyzers.

Within Run Precision testing consisted of one run of each of the following sample types and levels was performed, 20 replicates per run:

- Stat Profile Prime Plus Internal Controls: Levels 1- 5
- Stat Profile Prime Plus Ampuled Controls: Levels 1- 5
- Two whole bloods, sampled from syringes

To assess Run to Run Precision for whole blood, triplicate analyses were performed on a single whole blood sample in ten separate runs during a single day. The systems were recalibrated before each triplicate run.

The precision data for all parameters meet the within run imprecision specifications for the Stat Profile Prime Plus analyzers.

The precision data for all parameters meet the between analyzer run to run imprecision specifications for the Stat Profile Prime Plus analyzers.

Linearity Testing:

The study assessed the linearity of all parameters to establish and/or verify the Analytical Measurement Range (AMR) for the Stat Profile Prime Plus Analyzer on whole blood. The linearity was measured using method comparison. The evaluation of the linear range included lower and upper limits of the AMR and various medical decision limits.

All Stat Profile Prime Plus results were compared to the reference analyzer and/or the product specifications.

The linearity comparison data for all parameters for the Stat Profile Prime Plus analyzers shows good correlation and linearity to the reference analyzers across the claimed measurement range for all parameters and met the acceptance criteria.

Specificity / Interference Testing:

The purpose of this study was to identify substances that may interfere with the Stat Profile Prime Plus sensors. If interference was identified, a dose response study was performed to determine the concentration where the interfering substance may alter results.

This Interference Testing study was performed using whole blood collected in lithium heparin vacutainers. The possible interfering substances were tested at two analyte concentrations.

Many substances were screened as potential interferents through analysis on the Prime Plus analyzers. Substance screening was completed according to the CLSI EP7-A2 guideline. The interfering substances identified during the screening process are listed in the table below:

Parameter	Interfering Substance	Concentration of interfering substance	Interference
Glucose	Hydroxyurea	0.2 mg/dL	No interference observed
		0.4 mg/dL	Bias of 19.2%
	Oxalate	125 mg/dL	No interference observed
		250 mg/dL	Bias of -13.9%
	Thiocyanate	3.4 mmol/L	No interference observed
		5.1 mmol/L	Bias of 13.5%
Creatinine	Hydroxyurea	0.06 mg/dL	No interference observed
		0.08 mg/dL	Bias of 15.5%
	Thiocyanate	1.7 mmol/L	No interference observed
		3.4 mmol/L	Bias of 42.9%

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Conclusion:

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

Table 1: Comparison of Predicate and Proposed devices

Characteristic	Predicate: K110648 - Stat Profile pHOx Ultra Analyzer	Proposed: Stat Profile Prime Plus Analyzer
Indication For Use	The **Stat Profile 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 (Great) in heparinized whole blood, serum, or plasma. The **Stat Profile pHOx Ultra Analyzer with CO-Oximeter** is intended for in vitro diagnostic use by health care professionals and for point-of-care usage in the quantitative determination of pH, PCO_2, PO_2, SO_2%, Hematocrit (Hct), total Hemoglobin (tHb), Oxyhemoglobin (O_2Hb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), Deoxyhemoglobin (HHb), and total bilirubin (tBil) in heparinized whole blood; Nat, K'-, Cl-, Ca++, Mg++, Glucose (Glu), Lactate (Lac), BUN (Urea), and Creatinine (Creat) in Heparinized whole blood, serum, or plasma. Total Bilirubin (tBil) was not evaluated on neonatal samples.	The **Stat Profile Prime Plus Analyzer System** is indicated for use by healthcare professionals in clinical laboratory settings for quantitative determination of Glucose, Creatinine, and Blood Urea Nitrogen, in heparinized arterial and venous whole blood.
Acceptable Samples		
Sample Types	Sodium or lithium heparinized whole blood, serum, or plasma samples from syringes, open tubes, small cups, and capillary tubes.	Lithium heparin whole blood from syringes, open tubes, and small cups.
Sample Volumes	60-200µL (dependent on panel selected)	135µL
Measurement Range		
Glu	15 - 500 mg/dL	15 - 500 mg/dL
Creat	0.2 - 20.0 mg/dL	0.2 - 12.0 mg/dL
BUN	3 - 100 mg/dL	3 - 100 mg/dL
Principles of Measurement		
Glu	Enzymatic sensor	Same
Creat	Impedance sensor	Same
BUN	Enzymatic sensor	Same
Touch Screen	12.1" LCD, 1024x768 pixel, Resistive Touch	10.1" WXGA 1280 x 800 color touch screen
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