August 23, 2018

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

Re: K180186
Trade/Device Name: Stat Profile® Prime Plus Analyzer System
Regulation Number: 21 CFR 864.7500
Regulation Name: Whole blood hemoglobin assays
Regulatory Class: Class II
Product Code: GGZ, GKK, JPI, GHS, GKR
Dated: July 27, 2018
Received: July 31, 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 K180186

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 Hematocrit, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Met-hemoglobin, and Deoxyhemoglobin, in heparinized arterial and venous whole blood.

Hct	Hematocrit (Hct) measurements of the packed red blood cell volume are used to distinguish normal from abnormal states, such as anemia and erythrocytosis.
SO_2	Oxygen Saturation (SO_2) measurements are used to assess the oxygenation of the hemoglobin and the adequacy of tissue oxygenation in the evaluation of pulmonary function. Measurements are also used to diagnose and treat cyanosis.
tHb	Total Hemoglobin (tHb) measurements are used in the evaluation of chronic and acute anemia as well as the oxygen transport capability of the hemoglobin.
O_2Hb	Oxyhemoglobin (O_2Hb) measurements are used to assess pulmonary function in combination with Deoxyhemoglobin and are also used in the diagnosis and treatment of cyanosis.
COHb	Carboxyhemoglobin (COHb) measurements are used to determine if and to what level carbon monoxide has been inhaled by the patient. High levels of carbon monoxide can lead to tissue anoxia and death.
MetHb	Methemoglobin (MetHb) measurements are used to determine congenital methemoglobinemia or determine the ingestion of nitrates, chlorates, or any other drug or chemical that can cause methemoglobin formation. High levels of methemoglobin can lead to cyanosis and death.
HHb	Deoxyhemoglobin (HHb) measurements are used to assess pulmonary function in combination with Oxyhemoglobin.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K180186

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: August 23, 2018

Proprietary Name: Stat Profile Prime Plus Analyzer System

Common or Usual Name: Blood Analyzer

Classification Name: Multiple

Regulation section	Classification	Product code	Panel
21 CFR § 864.7500 Whole blood hemoglobin assays (Oxyhemoglobin)	Class II	GGZ	Hematology (81)
21 CFR § 864.7500 Whole blood hemoglobin assays (Cyanomethemoglobin)	Class II	GKK	
21 CFR § 864.6400 Hematocrit measuring device	Class II	JPI	
21 CFR § 864.7425 Carboxyhemoglobin assay	Class II	GHS	
21 CFR § 864.5620 Automated hemoglobin system	Class II	GKR	

Product Code: GGZ

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, calibrator packs, auto-cartridge quality control packs (internal controls), ampuled quality control materials (external controls) 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 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:
  - Hct, tHb, SO_2, O_2Hb, COHb, MetHb, HHb
- **Primary Sensor Card 2** shall enable and report the following listed analytes:
  - Hct, tHb, SO_2, O_2Hb, COHb, MetHb, HHb

Similar to the 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
- Instructions For Use (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:

- Oxygen Saturation (SO_2)
- Hematocrit (Hct)
- Total Hemoglobin (tHb)
- Oxyhemoglobin (O_2Hb)
- Carboxyhemoglobin (COHb)
- Methemoglobin (MetHb)
- Deoxyhemoglobin (HHb)

Intended Use:

The **Stat Profile Prime Plus Analyzer System** is indicated for use by healthcare professionals in clinical laboratory settings for quantitative determination of Hematocrit, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, and Deoxyhemoglobin, in heparinized arterial and venous whole blood.

Indications for Use:

Hct	Hematocrit (Hct) measurements of the packed red blood cell volume are used to distinguish normal from abnormal states, such as anemia and erythrocytosis.
SO_2	Oxygen Saturation (SO_2) measurements are used to assess the oxygenation of the hemoglobin and the adequacy of tissue oxygenation in the evaluation of pulmonary function. Measurements are also used to diagnose and treat cyanosis.
tHb	Total Hemoglobin (tHb) measurements are used in the evaluation of chronic and acute anemia as well as the oxygen transport capability of the hemoglobin.
O_2Hb	Oxyhemoglobin (O_2Hb) measurements are used to assess pulmonary function in combination with Deoxyhemoglobin and are also used in the diagnosis and treatment of cyanosis.

COHb	Carboxyhemoglobin (COHb) measurements are used to determine if and to what level carbon monoxide has been inhaled by the patient. High levels of carbon monoxide can lead to tissue anoxia and death.
MetHb	Methemoglobin (MetHb) measurements are used to determine congenital methemoglobinemia or determine the ingestion of nitrates, chlorates, or any other drug or chemical that can cause methemoglobin formation. High levels of methemoglobin can lead to cyanosis and death.
HHb	Deoxyhemoglobin (HHb) measurements are used to assess pulmonary function in combination with Oxyhemoglobin.

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:

Oxygen Saturation:

Oxygen saturation (SO2%) represents the percent of hemoglobin bound to oxygen, expressed as a fraction of the amount of hemoglobin capable of binding to oxygen (oxyhemoglobin plus deoxyhemoglobin). As the level of SO2% changes within a blood sample, the color of the whole blood changes. Oxygen Saturation is determined by using a standard equation.

Hematocrit:

Hematocrit is defined as the percentage of red blood cells to the total blood volume and can be obtained by measuring electrical resistance of the blood sample. Two standard solutions are used to calibrate the hematocrit sensor and to obtain the slope. The analyzer then measures the electrical resistance of the blood sample to obtain the hematocrit value. The hematocrit value obtained is corrected for the concentration of the sodium ion.

Total Hemoglobin:

Hemoglobin is a protein found in red blood cells that carries oxygen from the lungs to the body's tissues and returns carbon dioxide from the tissues back to the lungs.

Total Hemoglobin is the sum of all measured hemoglobin fractions expressed as the amount of hemoglobin in a specified volume of whole blood. Total Hemoglobin is calculated using a standard equation.

Oxyhemoglobin:

Oxyhemoglobin is the combined form of hemoglobin and oxygen. Oxygen is bound reversibly and is readily given up to the tissues because of the lower tissue oxygen tension. Conversely in the lungs, there is a higher oxygen tension and greater oxygen uptake by hemoglobin. The percentage of oxyhemoglobin is determined using a standard equation.

Carboxyhemoglobin:

Carboxyhemoglobin is the combined form of carbon monoxide and hemoglobin. The affinity of hemoglobin for carbon monoxide is approximately 210 times greater than for oxygen. Because of this high affinity, inhalation of large amounts of carbon monoxide can lead to death if left undiagnosed. The percentage of carboxyhemoglobin is determined by using a standard equation.

Methemoglobin:

Methemoglobin is the form of hemoglobin in which the iron has been oxidized from the ferrous to the ferric state. Oxygen cannot bind with methemoglobin. Therefore, increased amounts can lead to cyanosis, tissue anoxia, and death. There are congenital and acquired forms of methemoglobinemia. The percentage of methemoglobin is determined by using a standard equation.

Deoxyhemoglobin:

Deoxyhemoglobin is the form of hemoglobin that is not combined with oxygen but can easily uptake oxygen in the lungs. The percentage of deoxyhemoglobin is determined by using a standard 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 Hematocrit, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, and Deoxyhemoglobin in heparinized whole blood in a clinical laboratory setting.

The blood comparison data for Hematocrit, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, and Deoxyhemoglobin 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
Hct	Albumin	2.8 g/dL	No interference observed
		5.7 g/dL	Bias of 6
	Hemolysis	5%	No interference observed
		10%	Bias of -5
	Triglycerides	335.5 mg/dL	No interference observed
		503.2 mg/dL	Bias of 6
tHb	Evans Blue	0.25 mg/dL	No interference observed
		0.375 mg/dL	Bias of 0.8 g/dL
COHb	Evans Blue	0.25 mg/dL	No interference observed
		0.375 mg/dL	Bias of 2.0
	Sulfhemoglobin	0.803%	No interference observed
		1.116%	Bias of 2.4
O_2Hb	Evans Blue	0.125 mg/dL	No interference observed
		0.25 mg/dL	Bias of -4.1
	Sulfhemoglobin	0.631%	No interference observed
		0.803%	Bias of -4.2
MetHb	Evans Blue	0.125 mg/dL	No interference observed
		0.25 mg/dL	Bias of 3.0
	Patent Blue	1.875 mg/L	No interference observed
		2.5 mg/L	Bias of -2.2
	Methylene Blue	Interference at all concentrations	
	Sulfhemoglobin	0.631%	No interference observed
		0.803%	Bias of 2.3

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 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 Hematocrit, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, and Deoxyhemoglobin, 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		
SO_2	30-100%	Same
Hct	12-70%	Same
tHb	5.0 - 25.0 g/dL	Same
O_2Hb	0-100%	1.8-100%
COHb	0-100%	0.3-60%
MetHb	0-100%	0.3-60%
HHb	0-100%	0.4-40%
Principles of Measurement		
SO_2	Spectrophotometric	Same
Hct	Impedance sensor	Same
tHb	Spectrophotometric	Same
O_2Hb	Spectrophotometric	Same
COHb	Spectrophotometric	Same
MetHb	Spectrophotometric	Same
HHb	Spectrophotometric	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