January 24, 2020

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

Re: K193246
Trade/Device Name: Stat Profile Prime Plus Analyzer System
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: Class II
Product Code: CHL
Dated: November 8, 2019
Received: November 25, 2019

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

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 below.

510(k) Number *(if known)*
k193246

Device Name
Stat Profile Prime Plus Analyzer System

Indications for Use *(Describe)*
The Stat Profile Prime Plus Analyzer System is intended for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of pH, Partial Pressure of Carbon Dioxide (pCO_2) and Partial Pressure of Oxygen (pO_2) in heparinized arterial and venous whole blood.

pH, pCO_2 and pO_2 Measurements are used in the diagnosis and treatment of life-threatening acid base disturbances.

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
k193246

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: November 8, 2019

Proprietary Name: Stat Profile Prime Plus Analyzer System

Common or Usual Name: Blood Gas Analyzer

Classification Name: Blood Gases and Blood pH System

Product Code: CHL

Predicate Device: k173797 – 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:
  - PO_2, PCO_2, pH
- **Primary Sensor Card 2** shall enable and report the following listed analytes:
  - PO_2, PCO_2, pH

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
- 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:

- pH
- Partial Pressure of Carbon Dioxide (pCO_2)
- Partial Pressure of Oxygen (pO_2)

Calculated Parameters:

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

- Alveolar Oxygen (A)
- Arterial Alveolar Oxygen Tension Gradient ($A\text{-}aDO_2$)
- Arterial Alveolar Oxygen Tension Ratio (a/A)
- Arterial Oxygen Content (CaO_2)
- Arterial-Venous Oxygen Content Difference ($C(a\text{-}v)O_2$)
- Base Excess of Blood (BE-b)
- Base Excess of Extracellular Fluid (BE-ecf)
- Bicarbonate level (HCO_3)
- Capillary Oxygen Content (CcO_2)
- Oxygen Capacity (O_2Cap)
- Oxygen Content (O_2Ct)
- P_{50}
- pH corrected to patient temperature: pH(TC)
- pCO_2 corrected to patient temperature: $pCO_2(TC)$
- pO_2 corrected to patient temperature: $pO_2(TC)$
- PO_2 to FIO_2 Ratio (PO_2/FIO_2)
- Qsp/Qt (Physiological Shunt)
- Respiratory Index (RI)
- Standard Bicarbonate Concentration (SBC)
- Total Carbon Dioxide (TCO_2)
- Venous Oxygen Content (CvO_2)

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 pH, Partial Pressure of Carbon Dioxide (pCO_2), and Partial Pressure of Oxygen (pO_2) in heparinized arterial and venous whole blood.

pH, pCO_2, pO_2	Measurements are used in the diagnosis and treatment of life-threatening acid base disturbances.

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.

Principles of Measurement:

pH:

pH is measured using a hydrogen ion selective glass membrane. One side of the glass is in contact with a solution of constant pH. The other side is in contact with a solution of unknown pH. A change in potential develops which is proportional to the pH difference of these solutions. This change in potential is measured against a reference electrode of constant potential. The magnitude of the potential difference is a measure, then, of the pH of the unknown solution.

pCO_2:

pCO_2 is measured with a modified pH sensor. Carbon dioxide in the unknown solution makes contact with a gas permeable membrane mounted on a combination measuring/reference electrode. CO_2 diffuses across the membrane into a thin layer of electrolyte solution in response to partial pressure difference. This solution then becomes equilibrated with the external gas pressure. CO_2 in the solution becomes hydrated producing carbonic acid, which results in a change in hydrogen ion activity.

pO_2:

pO_2 is measured amperometrically by the generation of a current at the sensor surface. As oxygen diffuses through a gas permeable membrane, the oxygen molecules are reduced at the cathode, consuming 4 electrons for every molecule of oxygen reduced. This flow of electrons is then measured by the sensor and is directly proportional to the partial pressure of oxygen.

Summary of Performance Testing:

Bench testing was previously completed and summarized in k173797 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

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

Summary of Point-of-Care Testing:
A Point-of-Care (POC) study was conducted to demonstrate 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 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 & Arterial Whole Blood Method Comparison Results – POC vs Lab (ED, RT and CTICU)

								95% Confidence Interval of Bias	
Analyte	**N**	**# altered samples**	**range**	**Slope**	**Intercept**	**r**	**MDL**	**Lower Limit**	**Upper Limit**
pH	432	18	6.832 - 7.931	0.9930	0.0500	0.9976	7.1	7.099	7.102
							7.6	7.595	7.601
pO_2	432	18	11.5 - 555.2	1.0109	-1.5391	0.9989	40	38.4	40.6
							160	159.7	160.7
pCO_2	428	14	14.0 - 199.2	0.9848	0.9958	0.9963	20	19.6	20.9
							75	74.5	75.2

Total Imprecision Performance:
The estimates for total impression were obtained from different POC personnel running 3 levels of Stat Profile Prime Plus Quality Control 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 and is representative of the expected total imprecision performance obtainable by POC personnel using the Stat Profile Prime Plus analyzer using external quality control materials.

Table 2: Total Imprecision From ED Site

Blood Gas Quality Control, Level 1						
	Pooled Mean	N	Within Run SD	Within Run %CV	Total SD	Total %CV
pH	7.223	40	0.004	N/A	0.008	N/A
pCO_2 (mmHg)	60.0	40	1.6	2.6	3.6	5.9
pO_2 (mmHg)	76.5	40	1.3	1.6	2.4	3.1

Blood Gas Quality Control, Level 2						
pH	7.428	40	0.003	N/A	0.006	N/A
pCO_2 (mmHg)	37.2	40	1.1	3.0	2.3	6.1
pO_2 (mmHg)	112.2	40	1.6	1.4	3.0	2.6
Blood Gas Quality Control, Level 3						
pH	7.627	40	0.006	N/A	0.008	N/A
pCO_2 (mmHg)	20.1	40	0.6	3.1	1.0	4.8
pO_2 (mmHg)	148.9	40	1.6	1.1	3.4	2.3

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 two (2) point-of-care operators at each of the three (3) POC sites for a total of six (6) point-of-care operators across the 3 testing locations. Each precision run consisted of ten (10) replicate measurements using fresh, native whole blood samples. A total of five (5) different native 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

Sample 1				
	Mean	SD	%CV	95% CI
pH	7.287	0.011	N/A	7.265 - 7.308
pCO2 (mmHg)	50.6	0.82	1.62	49.0 - 52.2
pO2 (mmHg)	57.9	0.46	0.80	56.9 - 58.8
Sample 2				
pH	7.282	0.003	N/A	7.277 - 7.288
pCO2 (mmHg)	19.7	0.26	1.31	19.2 - 20.2
pO2 (mmHg)	66.7	1.34	2.01	64.0 - 69.3
Sample 3				
pH	7.405	0.005	N/A	7.395 - 7.415
pCO2 (mmHg)	31.0	0.22	0.70	3.05 - 31.4
pO2 (mmHg)	91.4	1.72	1.88	87.9 - 94.8
Sample 4				
pH	7.347	0.006	N/A	7.336 - 7.358
pCO2 (mmHg)	38.2	0.33	0.86	37.6 - 38.9
pO2 (mmHg)	643.0	30.44	4.73	582.1 - 703.9
Sample 5				
pH	7.396	0.003	N/A	7.389 - 7.402
pCO2 (mmHg)	34.5	0.39	1.14	33.7 - 35.3
pO2 (mmHg)	84.0	1.62	1.93	80.8 - 87.2

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 (k173797).

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 pH, Partial Pressure of Carbon Dioxide (pCO_2), and Partial Pressure of Oxygen (pO_2) 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 pH, Partial Pressure of Carbon Dioxide (pCO_2), and Partial Pressure of Oxygen (pO_2) 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		
pH	6.500 to 8.000 (pH units)	Same
PCO_2	3.0 to 200.0 mmHg	Same
PO_2	5.0 to 765 mmHg	Same
Principles of Measurement		
pH	Hydrogen ion-selective glass sensor	Same
PCO_2	Severinghaus-type sensor	Same
PO_2	Polarographic Clark-type sensor	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