



Food and Drug Administration  
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NOVA BIOMEDICAL CORPORATION  
PAUL MACDONALD  
CHIEF QUALITY AND REGULATORY AFFAIRS OFFICER  
200 PROSPECT ST.  
WALTHAM MA 02454

September 10, 2015

Re: K151982

Trade/Device Name: Stat Profile® Prime ABG Analyzer System  
Regulation Number: 21 CFR 862.1120  
Regulation Name: Blood gases (PCO<sub>2</sub>, PO<sub>2</sub>) and blood pH test system  
Regulatory Class: II  
Product Code: CHL  
Dated: July 16, 2015  
Received: July 17, 2015

Dear Paul Macdonald:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
**Katherine Serrano -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

## Indications for Use

510(k) Number (if known)  
k151982

Device Name

Stat Profile® Prime ABG Analyzer System

Indications for Use (Describe)

The Stat Profile Prime ABG Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings and for point-of-care usage for the quantitative determination of pH, PCO<sub>2</sub>, and PO<sub>2</sub> in heparinized whole blood.

PCO<sub>2</sub>, PO<sub>2</sub>, pH: Whole blood measurement of blood gases is 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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

**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:** Paul W. MacDonald  
**Date Prepared:** August 14, 2015

**Proprietary Name:** Stat Profile® Prime ABG Analyzer

**Common or Usual Name:** Blood gases (PCO<sub>2</sub>, PO<sub>2</sub>) and blood pH Test System

**Classification Name:** Multiple

Classification Names:	Class No.	Reg. No.	Class
Blood Gases and Blood pH system	75CHL	862.1120	II

**Product Codes:** CHL

**Predicate Device:** K142220 - Stat Profile® Prime ABG Analyzer System

### Device Description:

The Stat Profile® Prime ABG Analyzer is a small, low cost blood gas analyzer for laboratory and point-of-care use. The sensors and flow path have been integrated into one replaceable microsensor card, which is replaced periodically according to usage. The product, consumables, installation instructions and packaging are designed for easy customer installation.

Whole blood specimens are aspirated into the analyzer's microsensor card from syringes, tubes, or capillary blood collection devices using a peristaltic pump and a sampling probe. The disposable microsensor card contains the analytical flow path and the measurement sensors (pH, PCO<sub>2</sub>, and PO<sub>2</sub>). Once the analysis measurement is complete, the whole blood specimen is automatically flushed out of the microsensor card flow path and into a self-contained waste collection bag contained within the disposable calibrator cartridge.

The Stat Profile Prime ABG Analyzer has an enhanced test menu and multiple quality control options. Both traditional Internal and External liquid QC shall be offered, as well as an on-board Quality Management System (QMS), an electronic monitoring approach that insures the analyzer is working properly.

As with the predicate, the Stat Profile Prime ABG Analyzer is microprocessor-based and incorporates:

- traditional sensor technology to measure blood pO<sub>2</sub>
- ion selective electrode technology to measure pH and pCO<sub>2</sub>

The following items are intended for use on the Stat Profile Prime ABG Analyzer and were previously cleared on the predicate Stat Profile Prime ABG Analyzer System, k142220:

The Stat Profile Prime Auto QC Cartridge ABG is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of the Stat

## Profile Prime ABG Analyzer.

The Stat Profile Prime Ampule Control ABG/CCS is a quality control material intended for in vitro diagnostic use by healthcare professionals for monitoring the performance of Stat Profile Prime ABG Analyzer.

The Stat Profile Prime Calibrator Cartridge ABG is intended for the calibration of pH, PCO<sub>2</sub>, and PO<sub>2</sub> using the Stat Profile Prime ABG Analyzer.

The Stat Profile Prime ABG Analyzer accepts Lithium heparin whole blood sample from syringes, open tubes, small cups, and capillary tubes. The minimum sample size for both syringe and capillary samples analysis is 50 µL.

### Measured Parameters:

The Stat Profile Prime ABG Analyzer measures pH, PCO<sub>2</sub>, and PO<sub>2</sub>.

### Calculated Parameters:

- pH, PCO<sub>2</sub>, PO<sub>2</sub> (corrected to patient temperature)
- Bicarbonate level (HCO<sub>3</sub><sup>-</sup>)
- Total Carbon Dioxide (TCO<sub>2</sub>)
- Base Excess of the blood (BE-b)
- Base Excess of extracellular fluid (BE-ecf)
- Standard Bicarbonate Concentration (SBC)
- Oxygen Content (O<sub>2</sub>Ct)
- Oxygen Capacity (O<sub>2</sub>Cap)
- Alveolar Oxygen (A)
- Arterial Alveolar Oxygen Tension Gradient (AaDO<sub>2</sub>)
- Arterial Alveolar Oxygen Tension Ratio (a/A)
- Respiratory Index (RI)
- PO<sub>2</sub>/FIO<sub>2</sub> ratio
- Oxygen Saturation (SO<sub>2</sub>%)

### Intended Use:

The Stat Profile Prime ABG Analyzer is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings and for point-of-care usage for the quantitative determination of pH, PCO<sub>2</sub>, and PO<sub>2</sub> in heparinized whole blood.

PCO<sub>2</sub>, PO<sub>2</sub>, pH      Whole blood measurement of blood gases is used in the diagnosis and treatment of life-threatening acid-base disturbances in critically ill patients with numerous metabolic and pulmonary diseases.

### Summary of the Technological Characteristics:

The Stat Profile Prime ABG Analyzer is substantially equivalent to the previously cleared Stat Profile Prime ABG Analyzer System in intended use. It uses the same sensor technology and measurement algorithms for pH, PCO<sub>2</sub>, and PO<sub>2</sub>, and the formulations of the internal and external controls and the calibration cartridge are the same for the tested parameters.

### Summary of Performance Testing:

Bench testing was previously completed to demonstrate that the Stat Profile Prime ABG Analyzer is substantially equivalent in performance, safety and efficacy in the predicate submission.

The bench testing included:

- Method Comparison Studies
- Precision/Reproducibility Studies
- Run to Run Precision
- Within Run Precision

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

### Summary of Point-of-Care Testing

A Point-of-Care study was conducted to demonstrate that the analyzer was safe and effective for use in the POC setting. 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 ABG Analyzer was evaluated by point-of-care (POC) personnel in 3 POC sites including a cardiovascular intensive care unit (CVICU), a medical intensive care unit (MICU) and a pulmonary care unit (PCU). A total of 35 respiratory therapy and 17 Nursing 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.

Combined method comparison data from all 3 POC settings is summarized in Tables 2-1 and 2-2.

**Table 2-1: Prime ABG: POC v Trained Healthcare Professional (THP) - Syringe Mode**

Parameter	Total # specimens	Whole Blood Range	Slope	Intercept	r
pH	188	6.785 - 7.767	0.997	0.018	0.999
PCO <sub>2</sub> mmHg	188	4.3 - 193.0	1.001	1.063	0.998
PO <sub>2</sub> mmHg	188	11.8 - 755.3	1.015	-0.939	1.000

**Table 2-2: Prime ABG: POC v Trained Healthcare Professional (THP) - Capillary Mode**

Parameter	Total # specimens	Whole Blood Range	Slope	Intercept	r
pH	127	6.791 - 7.737	0.993	0.047	0.998
PCO <sub>2</sub> mmHg	127	3.2 - 192.2	0.984	1.347	0.997
PO <sub>2</sub> mmHg	127	13.1 - 672.9	1.041	-2.761	0.999

### Total Imprecision Performance

The total imprecision data included in the following table was obtained from different POC site personnel running 3 levels of Stat Profile Prime External Quality Control material (Levels 1-3) in duplicate each day for a total of 20 runs on 3 Stat Profile Prime ABG analyzers. The protocol was based upon methods described in CLSI "Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second edition," CLSI EP5-A2. The test data is representative of the expected total imprecision between analyzer performances obtainable by POC personnel using the Stat Profile Prime ABG analyzer using external quality control materials.

**Table 2-3: Prime ABG: Total Imprecision Results – Combined – External Controls**

Point-of-Care Study - Stat Profile Prime External Quality Control Materials (N=20 runs)

Parameter	Pooled Mean	N	Within Run SD (Sr)	Within Run %CV	Total Imprecision SD (St)	Total Imprecision %CV
Combined Total Imprecision Data - Level 1						
pH	7.152	120	0.004	0.056	0.005	0.070
PCO <sub>2</sub>	61.3	120	0.8	1.3	1.7	2.7
PO <sub>2</sub>	64.0	120	1.6	2.5	3.2	5.0
Combined Total Imprecision Data - Level 2						
pH	7.367	120	0.002	0.027	0.003	0.041
PCO <sub>2</sub>	41.4	120	0.4	1.0	0.6	1.5
PO <sub>2</sub>	101.7	120	1.4	1.4	3.0	2.9
Combined Total Imprecision Data - Level 3						
pH	7.560	120	0.006	0.079	0.007	0.093
PCO <sub>2</sub>	25.5	120	0.8	3.1	1.2	4.7
PO <sub>2</sub>	139.8	120	1.7	1.2	4.0	2.8

**Table 2-4: Comparison of Predicate and Proposed devices**

Characteristic	K142220 - Stat Profile® Prime ABG Analyzer	Proposed: Stat Profile® Prime ABG Analyzer
Indication For Use	The Stat Profile Prime ABG Analyzer System is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings for the quantitative determination of pH, PCO <sub>2</sub> , and PO <sub>2</sub> in heparinized whole blood.	The Stat Profile Prime ABG Analyzer is intended for in vitro diagnostic use by health care professionals in clinical laboratory settings and for point-of-care usage for the quantitative determination of pH, PCO <sub>2</sub> , and PO <sub>2</sub> in heparinized whole blood.
Acceptable Samples	PCO <sub>2</sub> , PO <sub>2</sub> , pH - Whole blood measurement of blood gases is used in the diagnosis and treatment of life-threatening acid-base disturbances in critically ill patients with numerous metabolic and pulmonary diseases.	Same
Sample Volumes	Lithium heparinized whole blood from syringes, open tubes, small cups, and capillary tubes. 50µL (syringe and capillary)	Same
Measurement Range		
pH	6.500-8.000	Same
PCO2	3.0 -200 mmHg	Same
PO2	5-765 mmHg	Same
Principles of Measurement		
pH	Hydrogen ion-selective sensor	Same
PCO2	Severinghaus-type sensor	Same
PO2	Polarographic Clark-type sensor	Same
Touch Screen	5.7" VGA full color display with LED backlight and integrated touch panel	Same

Characteristic	K142220 - Stat Profile® Prime ABG Analyzer	Proposed: Stat Profile® Prime ABG Analyzer
Menu	Fully configurable test menu based on above 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/ amperometrically and potentiometric amplifiers, air detector circuitry and temperature control circuitry	Same

**Conclusion:**

The results of software validation and performance verification testing confirmed that the Stat Profile Prime ABG Analyzer is safe and effective for its intended purpose and that the Stat Profile Prime ABG Analyzer is substantially equivalent to that of the predicate Stat Profile Prime ABG Analyzer System (K142220).