DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 22 2002

Mr. Paul W. MacDonald
Director of Quality Assurance/Regulatory Affairs
Nova Biomedical
200 Prospect Street
Waltham, MA 02454-9141

Re: k022746
Trade/Device Name: Stat Profile Critical Care Xpress Analyzer
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases ($P_{CO}2$, P_02) and blood pH test system
Regulatory Class: Class II
Product Code: CHL; JGS; CEM; JFP; CGZ; CGL; CFA; CGA; KHP; CDS; JKS; JPI; GKR; GHS; JIX; JPK; JJS
Dated: October 30, 2002
Received: October 31, 2002

Dear Mr. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K022746

Device Name: Stat Profile Critical Care Xpress Analyzer

Indications for Use:

Intended Use

The Stat Profile Critical Care Xpress Analyzer is intended for *in vitro* diagnostic use by health care professionals and for point-of-care usage in the quantitative determination of pH, *P*CO2, *P*O2, *S*O2%, Hematocrit (Hct), Ca++, total Hemoglobin (tHb), Oxyhemoglobin (O2Hb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), Reduced Hemoglobin (HHb), Oxygen content (O2Ct), and Oxygen capacity (O2Cap) 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.

Clinical Utility [1,2]
The following list includes the clinical utility information for each of the analytes measured on the STP Critical Care Xpress Analyzer.

Blood Gases: (PCO_2, PO_2, and 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.

Oxygen Saturation (SO_2)

Used to assess the oxygenation of hemoglobin and the adequacy of tissue oxygenation in the evaluation of pulmonary function. Also used in the diagnosis and treatment of cyanosis.

Hematocrit (Hct)

Whole blood measurement of hematocrit is used to estimate that red blood cells are present in sufficient quantity to carry oxygen and carbon dioxide.

Hemoglobin (Hb)

Oxygen is carried from the lungs throughout the body by hemoglobin present in red blood cells. Measurement of hemoglobin (tHb) provides the clinician with information regarding the evaluation of chronic and acute anemias and also with information pertaining to the potential oxygen transport capability of the hemoglobin.

Oxyhemoglobin (O_2Hb)

The fraction of total hemoglobin combined with oxygen. O_2Hb is used to assess pulmonary function. Also used in the diagnosis and treatment of cyanosis.

Carboxyhemoglobin (COHb)

Measurement of carboxyhemoglobin indicates if and to what level carbon monoxide has been inhaled by the patient. Because the affinity of hemoglobin for carbon monoxide is approximately 210 times greater than the affinity for oxygen, high levels of carbon monoxide can lead to tissue anoxia and death unless diagnosed early.

Methemoglobin (MetHb)

Elevations in methemoglobin concentration can be due to congenital methemoglobinemia or from the ingestion of nitrates, chlorates, or any other drug or chemical that can cause methemoglobin formation. Methemoglobin cannot bind with oxygen. Cyanosis and eventually death may occur if left untreated.

Sodium (Na+)

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

Potassium (K+)

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

Chloride (Cl-)

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

Ionized Calcium (Ca++)

Used in the diagnosis and treatment of hypertension, renal disease, and vitamin D related disorders. Also useful in the diagnosis and treatment of patients with increased total protein and/or albumin levels, as in dehydration.

Ionized Magnesium (Mg++)

Measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low levels of magnesium) and hypermagnesemia (abnormally high levels of magnesium).

Creatinine (Creat)

Measurement of creatinine is used in the diagnosis and treatment of certain renal conditions and is used for monitoring adequacy of dialysis, for example, peritoneal dialysis and peritoneal equilibration testing.

Glucose — Measurement of glucose is used in the diagnosis and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Lactate — Measurement of lactic acid (lactate) in whole blood, serum, and plasma is used to evaluate the acid-base status of patients suspected of having lactic acidosis.

Urea Nitrogen (BUN)

Measurement of urea nitrogen is used in the diagnosis and treatment of certain renal and metabolic diseases.

Ref. 1. Tietz, N.W. ed. 1986. *Textbook of Clinical Chemistry.* W. B. Saunders Co

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022446

(Optional Format 3-10-98)

Rx