



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

**JUN 10 2002**

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

Re: k020297  
Trade/Device Name: Stat Profile Critical Care Xpress Analyzer  
Regulation Number: 21 CFR 862.1120  
Regulation Name: Blood gases( $P_{CO_2}$ ,  $P_{O_2}$ ) and blood pH test system  
Regulatory Class: Class II  
Product Code: CHL  
Dated: April 12, 2002  
Received: April 15, 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 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); 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.

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This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory-Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number:

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 for the quantitative determination of pH, pCO<sub>2</sub>, pO<sub>2</sub>, SO<sub>2</sub>%, Hct, Hb, Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, Mg<sup>++</sup>, Glu, BUN, Lac and Creat in heparinized whole blood, and Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, Mg<sup>++</sup>, Glu, BUN, Lac and Creat in serum and plasma.

#### Clinical Utility<sub>1</sub>

The following list includes the clinical utility information for each of the analytes measured on the CCX Analyzer.

**Blood Gases (PCO<sub>2</sub>, PO<sub>2</sub> 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:** 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:** 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:** Oxygen is carried from the lungs throughout the body by hemoglobin present in red blood cells. Measurement of hemoglobin 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.

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

**Potassium:** 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:** Measurement of chloride is used in the diagnosis and treatment of electrolyte

and metabolic disorders such as cystic fibrosis and diabetic acidosis.

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

**Creatinine:** 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.

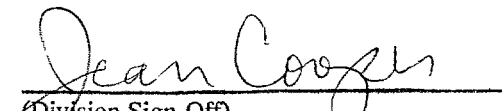
**Urea Nitrogen:** Measurement of urea nitrogen is used in the diagnosis and treatment of certain renal and metabolic diseases.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

  
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(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K020297