K03/560
page 1 of 5

DEC 17 2003

Appendix A
Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. **Submitters Information**

Contact person:	Mary E. Gray, RAC NPT Regulatory Affairs Manager
Address:	Bayer Healthcare, LLC Bayer Corporation 63 North Street Medfield, MA 02052
Phone:	(508) 359-3825
e-mail address:	mary.gray.b@bayer.com
Date Summary Prepared:	December 11, 2003

2. **Device Information**

Proprietary Name:	Rapidlab 1200 System Series
Common Name:	Analyzer for Blood Gas, Electrolyte, Metabolite and CO-oximetry
Classification Name:	Blood gases and blood pH test system

Classification Number:

pH -	21 CFR 862.1120, Class II
*p*CO2 -	21 CFR 862.1120, Class II
*p*O2 -	21 CFR 862.1120, Class II
Calcium -	21 CFR 862.1145, Class II
Chloride -	21 CFR 862.1170, Class II
Potassium -	21 CFR 862.1600, Class II
Sodium -	21 CFR 862.1665, Class II
Glucose -	21 CFR 862.1345, Class II
Lactate -	21 CFR 862.1450, Class II
CO-oximetry Parameters	21 CFR 864.5620, Class II

3. **Predicate Device Information**

Name:	Rapidlab 800 Series	Rapidpoint 400 Series
Manufacturer:	Bayer Healthcare, LLC	Bayer Healthcare, LLC
510(k) Number:	# K934907 # K946206	# K002738 # K020616

Appendix A
Summary of Safety and Effectiveness

4. **Device Description**

The Rapidlab 1200 system series is intended for laboratory testing of blood gases, electrolytes, metabolites and CO-oximetry in arterial, venous and capillary whole blood samples.

5. **Statement of Intended Use**

The Rapidlab 1200 System is intended for in vitro diagnostic use by healthcare professionals in the quantitative testing of samples of whole blood for the following parameters:

- partial pressures of carbon dioxide; pCO_2
- partial pressure of oxygen pO_2
- pH
- sodium; Na^+
- potassium; K^+
- ionized calcium; Ca^{++}
- chloride; Cl^-
- glucose
- lactate
- CO-oximetry parameters (tHb, FO2Hb, FCOHb, FMetHb, FHHb)

6. **Statement of Indications for Use**
The following list includes the indication for use information for each analyte measured on the Rapidlab 1200 System Series:

pCO_2, pO_2, pH. Measurements of blood gases (PCO2, PO2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Sodium. Sodium measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Potassium. Potassium measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Ionized calcium. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Glucose. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Lactate. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Total hemoglobin. Total hemoglobin measurements are used to determine the hemoglobin content of human blood.

Oxyhemoglobin. Oxyhemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

Carboxyhemoglobin. Carboxyhemoglobin measurements are used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

Sulfhemoglobin. Sulfhemoglobin measurements are used to determine the sulfhemoglobin (a compound of sulfur and hemoglobin) content of human blood as an aid in the diagnosis of sulfhemoglobinemia (presence of sulfhemoglobin in the blood due to drug administration or exposure to a poison).

7. **Summary of Clinical Utility**

The following list includes the clinical utility information for each analyte measured on the Rapidlab 1200 System Series:

pH. Acidosis (low pH) stems from either respiratory failure (high pCO_2) or from metabolic causes (including ketoacidosis, lactic acidosis, uremia, severe diarrhea, hypoaldosteronism, renal tubular disease, drug effects, or poisoning from several specific agents). Alkalosis (high pH) stems from hyperventilation (low pCO_2) or from metabolic causes (including excessive vomiting, gastric drainage, drug effects, hyperadrenocorticism, potassium depletion, or excessive alkalai intake). Extreme abnormalities of pH reflect a potentially life-threatening pathophysiologic state that must be corrected promptly.

pCO_2. This analyte reflects the overall respiratory status. Thus high pCO_2 indicates respiratory suppression or failure, whereas low pCO_2 indicates hyperventilation (which in turn may stem from hypoxia, anxiety, fever, cerebral disease, cirrhosis, or excessive mechanical ventilation). Extreme abnormalities of pCO_2 reflect a potentially life-threatening pathophysiologic state that must be corrected promptly.

pO_2. This analyte reflects the ability of the lungs to deliver oxygen to the blood. Hypoxia (low pO_2) may occur despite adequate respiration due to parechymal lung diseases (e.g. pneumonia, asthma, pulmonary edema, and pulmonary fibrosis) due to pulmonary shunting of blood. Extremely low pO_2 is a potentially life-threatening pathophysiologic state that must be corrected promptly.

Sodium. Abnormal concentrations stem from deficit or overload of total body water or of sodium itself. These arise from diverse clinical conditions such as congestive heart failure, liver disease (cirrhosis), renal disease, neuropsychiatric disorders (causing abnormal fluid intake), intravenous fluid therapy, excessive fluid loss (e.g. vomitting, diarrhea, heat stroke), drug therapy (e.g. diuretics), diabetes mellitus (causing osmotic diuresis), and imbalances of hormones (e.g. ADH, mineralcorticoid, glucocorticoid) which regulate sodium and water excretion. An extremely abnormal plasma sodium concentration may itself directly cause altered mental status, stupor, coma, seizures, brain swelling, brain dehydration leading to cerebral hemorrhage, or, ultimately, death. Thus extreme abnormalities of sodium reflect a potentially life-threatening pathophysiologic state that must be corrected promptly.

Potassium. High concentrations commonly stem from renal insufficiency (or failure), excessive potassium replacement, drug effects (including some diuretics), hemolytic disease, or crush injury. Low concentrations stem from gastrointestinal loss, dietary insufficiency, or drug effects (most diuretics). Other metabolic imbalances (acid-base, mineralcorticoid, glucocorticoid, insulin effects) also cause abnormal potassium concentrations. An extremely abnormal plasma potassium concentration may itself directly cause neuromuscular paralysis, respiratory failure, cardiac arrhythmia, or cardiac arrest. Thus extreme abnormalities of potassium reflect a potentially life-threatening pathophysiologic state that must be corrected promptly.

Chloride. Assay is used most commonly to distinguish the "high anion gap" acidoses (ketoacidosis, lactic acidosis, uremia, poisoning from several specific agents) from "hyperchloremic" acidoses (loss of alkalai as in severe diarrhea, hypoaldosteronism, potassium-sparing diuretics, renal tubular acidosis). In the absence of acidosis, changes in plasma choride concentration tend to parallel those of sodium. Thus chloride is high in dehydration and low in overhydrated states.

Ionized calcium. Abnormalities typically stem from parathyroid disease, vitamin D imbalance, renal disease, pancreatitis, drug effects, abnormalities of magnesium or phosphorus, malignancy, or sarcoidosis. An extreme abnormality itself may cause neuromuscular symptoms, tetany, altered mental status, seizures, heart failure, or arrhythmias. Thus extreme abnormalities of ionized calcium reflect a potentially life-threatening pathophysiologic state that must be corrected promptly.

Glucose. Glucose is elevated in any of the forms of diabetes mellitus, including Type 1, Type 2, Gestational, or any of the 50 "Other Specific Types." More moderate elevations occur in pre-diabetic conditions known as "impaired glucose levels." Diabetics sometimes suffer acute, life-threatening metabolic crises known as "diabetic ketoacidosis" which is typical in Type 1, or "hyperglycemic hyperosmolar nonketotic state" which is typical in Type 2. Low glucose levels most commonly stem from insulin overdose, but also from a number of disorders collectively know as "hypoglycemic disorders." Examples of the latter include insulinoma, IGF_2-secreting tumor, factitious hypoglycemia, postprandial syndrome, severe hepatic disorders, endocrine disorders characterized by deficiencies in gluconeogenic hormones, and some post-surgical gastric states. Extreme abnormalities of glucose reflect a potentially life-threatening pathophysiologic state that must be corrected promptly.

Lactate. Elevations are a sign of inadequate delivery oxygen to the peripheral tissues as occurs in respiratory failure, circulatory failure, and clinical shock.

Total hemoglobin. Hemoglobin is low in anemia. There are numerous specific types of anemia, but each stems from one of three basic causes: blood loss, destruction of red blood cells, or failure to produce new red blood cells. Hemoglobin is high in polycythemia, which may be primary, secondary to hypoxia, secondary to dehydration, or a complication of over-transfusion. Polycythemia may lead to circulatory complications as a result of increased blood viscosity. Extreme abnormalities of hemoglobin reflect a potentially life-threatening pathophysiologic state that must be corrected promptly.

Oxyhemoglobin. This is the fraction of hemoglobin that is actually delivering oxygen to body tissues.

Reduced hemoglobin. This is the fraction of hemoglobin that could deliver more oxygen to body tissues if pulmonary oxygenation were improved.

Carboxyhemoglobin. This is a fraction of hemoglobin that cannot deliver oxygen to body tissues. It is formed when carbon monoxide is inhaled.

Methemoglobin. This is a fraction of hemoglobin that cannot deliver oxygen to body tissues. It is elevated in certain metabolic diseases.

Sulfhemoglobin. This is a fraction of hemoglobin that cannot deliver oxygen to body tissues. It may be elevated in some patients taking sulfur-containing drugs or with certain infections.

8. Summary of Technological Characteristics

The 1200 Series System uses measurement technology that is based on electrochemical, biochemical and optical phenomena. The device use potentiometry and amperometry methods for blood gas, electrolytes and metabolites to convert the potential generated by the sensor to an electrical signal which the system then converts to a value that represents that concentration of a specific analyte or substances in recognizable units of measurement.

The Rapidlab 1200 series system CO-oximetry module utilizes spectral absorption by measuring the light from whole blood at several wavelengths. The measurement module detects and quantitates total hemoglobin and other related quantities in the sample.

The Rapidlab 1200 series system will interface with the Rapidlink information management system and/or will provide connect capability to hospital LIS/HIS systems via network interface ports.

The Rapidlab 1200 systems are similar in technological characteristics, device performance and intended use therefore are substantially equivalent to the predicate devices, the Rapidlab 800 and the Rapidpoint 400 analyzers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 2003

Ms. Mary E. Gray
NPT Regulatory Affairs Manager
Bayer HealthCare LLC
Diagnostics Division
63 North Street
Medfield, MA 02052

Re: k031560
Trade/Device Name: Bayer Diagnostics Rapidlab 1200 System Series
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (Pco2, Po2) and blood pH test system
Regulatory Class: Class II
Product Code: CHL; JFP; CGZ; CEM; JGS; CGA; GKR; KHP
Dated: October 1, 2003
Received: October 2, 2003

Dear Ms. Gray:

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). You may obtain other general information on your responsibilities under the Act 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

Bayer HealthCare
Diagnostics Division

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K031560

Device Name: Bayer Rapidlab 1200 System

Intended Use:

The Rapidlab 1200 system series is intended for in vitro diagnostic use by healthcare professionals in the quantitative testing of samples of whole blood for the following parameters:

- partial pressure of carbon dioxide
- partial pressure of oxygen
- pH
- sodium
- potassium
- ionized calcium
- chloride
- glucose
- lactate
- CO-oximetry parameters (tHb, FO2Hb, FCOHb, FMetHb, FHHb)

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031560

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Indications for Use:

The following list includes the indication for use information for each analyte measured on the Rapidlab 1200 System Series:

pCO_2, pO_2, pH. Measurements of blood gases (PCO2, PO2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Sodium. Sodium measurements obtained by this device are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.

Potassium. Potassium measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

Chloride. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Ionized calcium. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Glucose. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031560

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Lactate. Lactic acid measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Total hemoglobin. Total hemoglobin measurements are used to determine the hemoglobin content of human blood.

Oxyhemoglobin. Oxyhemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

Carboxyhemoglobin. Carboxyhemoglobin measurements are used to determine the carboxyhemoglobin (the compound formed when hemoglobin is exposed to carbon monoxide) content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

Sulfhemoglobin. Sulfhemoglobin measurements are used to determine the sulfhemoglobin (a compound of sulfur and hemoglobin) content of human blood as an aid in the diagnosis of sulfhemoglobinemia (presence of sulfhemoglobin in the blood due to drug administration or exposure to a poison).

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031560

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)