Summary of Safety and Effectiveness

Liquichek™ Blood Gas Plus CO-Oximeter Control (IL Synthesis Series)

1.0 Submitter

Bio-Rad Laboratories
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Date of Summary Preparation

July 24, 2002

2.0 Device Identification

Product Trade Name:	Liquichek™ Blood Gas Plus CO-Oximeter Control (IL Synthesis Series) Levels 1, 2, and 3
Common Name:	Controls for Blood Gases, (Assayed and Unassayed)
Classifications:	Class I
Product Code:	JJS
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek™ Blood Gas Plus CO-Oximeter Control (IL)
Bio-Rad Laboratories
Irvine, California

Docket Number: K003242

4.0 Description of Device

Liquichek™ Blood Gas Plus CO-Oximeter Control (IL Synthesis Series) is a dye based, buffered bicarbonate and electrolyte solution in equilibrium with pre-determined levels of oxygen, carbon dioxide, nitrogen and glucose.

5.0 Statement of Intended Use

Liquichek™ Blood Gas Plus CO-Oximeter Control (IL Synthesis Series) is an assayed quality control intended for use in monitoring the precision of an individual laboratory's measurement of pH, pCO_2, pO_2, electrolytes, glucose, total hemoglobin, and hemoglobin fractions by blood gas, ion selective electrode (ISE), biosensor and IL Synthesis CO-Oximetry instrumentation.

6.0 Comparison of the new device with the Predicate Device

The new Liquichek™ Blood Gas Plus CO-Oximeter Control (IL Synthesis Series) claims substantial equivalence to the Liquichek™ Blood Gas Plus CO-Oximeter Control (IL) currently in commercial distribution (K003242).

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio Rad Liquichek™ Blood Gas Plus CO-Oximeter Control (IL Synthesis Series) (New Device)	Bio Rad Liquichek™ Blood Gas Plus CO-Oximeter Control (IL) (Predicate Device)
Similarities		
Levels	Three	Three
Form	Liquid	Liquid
Matrix	Buffered bicarbonate and electrolyte solution	Buffered bicarbonate and electrolyte solution
Shelf Life	3 years when stored unopened at 2 – 8°C	3 years when stored unopened at 2 – 8°C
Fill Volume	1.7 mL	1.7 mL
Differences		
Intended Use	An assayed quality control to monitor the precision of an individual laboratory's measurement of pH, pCO_2, pO_2, electrolytes, glucose, total hemoglobin, and hemoglobin fractions by blood gas, ion selective electrode (ISE), biosensor and IL Synthesis CO-Oximetry instrumentation.	An assayed quality control to monitor the precision of an individual laboratory's measurement of pH, pCO_2, pO_2, electrolytes, glucose, lactate (lactic acid), total hemoglobin, and hemoglobin fractions by blood gas, ion selective electrode (ISE), IL CO-Oximetry, and biosensor instrumentation.
Op n Vial Claim	When the control is used for pH and blood gas measurements, the material should be sampled immediately after opening. When used only for Co-Oximeter,	When the control is used for pH and blood gas measurements, the material should be sampled immediately after opening. When used only for Co-Oximeter,

	electrolyte, and glucose measurements, the material should be sampled within 10 minutes of opening to avoid evaporation. Once the control is sampled, discard remaining material.	electrolyte, glucose or lactate measurements, the material should be sampled within 10 minutes of opening to avoid evaporation. Once the control is sampled, discard remaining material.
Storage Stability	6 months when stored unopened at room temperature (20 – 25°C).	12 months when stored unopened at room temperature (20 – 25°C).
Instrument	Made to run on the IL Synthesis CO-Oximetry instrumentation.	Made to run on the IL CO-Oximetry instrumentation.
Claimed Analytes	pH, pCO2, pO2, Calcium-ionized, Chloride, Potassium, Sodium, Glucose, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, Reduced Hemoglobin, and Oxygen Saturation.	pH, pCO2, pO2, Calcium-ionized, Chloride, Potassium, Sodium, Glucose, Lactate (Lactic Acid), Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, Reduced Hemoglobin, Volume Percent Oxygen and Volume Percent Oxygen Capacity.

7.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ Blood Gas Plus CO-Oximeter Control (IL Synthesis Series). Product claims are as follows:

1. Open vial: When the control is used for pH and blood gas measurements, the material should be sampled immediately after opening. When used only for CO-Oximeter, electrolyte, and glucose measurements, the material should be sampled within 10 minutes of opening to avoid evaporation. Once the control is sampled, discard remaining material.

2. Unopened vials of the control will be stable for 3 years when stored at 2-8°C. The control may be stored unopened at room temperature (20 to 25°C) for 6 months, but should not be used past the expiration date **(note the date room temperature storage begins).** Avoid exposures to temperatures 2°C or above 30°C. Do not store in direct sunlight.

Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 15 2002

Ms. Elizabeth Platt
Regulatory Affairs/Quality Assurance Manager
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k022529
Trade/Device Name: Liquichek™ Blood Gas Plus Co-Oximeter Control (IL Synthesis Series)
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJS
Dated: July 24, 2002
Received: July 31, 2002

Dear Ms. Platt:

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.

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,

Steven Gutman

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

510 (k) Number (if known): K022529

Device Name: **Liquichek™ Blood Gas Plus Co-Oximeter Control (IL Synthesis Series)**

Indications for Use:

Liquichek™ Blood Gas Plus Co-Oximeter Control (IL Synthesis Series) is an assayed quality control intended for use in monitoring the precision of an individual laboratory's measurement of pH, pCO_2, pO_2, electrolytes, glucose, total hemoglobin, and hemoglobin fractions by blood gas, ion selective electrode (ISE), biosensor and IL Synthesis Co-Oximetry instrumentation.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022529

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use ____