K123198

Summary of Safety and Effectiveness

Liquichek Ethanol/Ammonia Control

1.0 **Submitter**

NOV 20 2012

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
Telephone: (949) 598-1200
Fax: (949) 598-1557

Contact Person

Suzanne Parsons
Regulatory Affairs Manager
Telephone: (949) 598-1467

Date of Summary Preparation

November 15, 2012

2.0 **Device Identification**

Product Trade Name:	Liquichek Ethanol/Ammonia Control
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Classifications:	Class I, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 **Device to Which Substantial Equivalence is Claimed**

Predicate Device Information	
Device Name:	Liquichek Ethanol/Ammonia Control
Applicant:	Bio-Rad Laboratories
510(k) Number:	K955024
Product Code:	JJY
Regulation #:	862.1660
Device Classification Name:	Multi-analyte Controls, All Kinds(Assayed)

4.0 **Description of Device**

Liquichek Ethanol/Ammonia Control is prepared from bovine serum albumin with chemicals, stabilizers and preservatives added. This control is provided in liquid form for convenience.

5.0 **Intended Use**

Liquichek Ethanol/Ammonia Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

6.0 Value Assignment

The mean values and the corresponding ±3SD ranges printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications

7.0 Comparison of the new device with the Predicate Device

Liquichek Ethanol/Ammonia Control claims substantial equivalence to the Liquichek Ethanol/Ammonia Control currently in commercial distribution under 510(k)K955024. Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

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

Characteristics	Liquichek Ethanol/Ammonia Control (New Device)	Liquichek Ethanol/Ammonia Control (Predicate Device under K955024)
Similarities		
Intended Use	Liquichek Ethanol/Ammonia Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.	Liquichek Ethanol/Ammonia Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.
Matrix	This product is prepared from bovine serum albumin with added chemicals, stabilizers and preservatives.	This product is prepared from bovine serum albumin with added chemicals, stabilizers and preservatives.
Form	Liquid	Liquid
Storage unopened (Shelf life)	Until the expiration date when stored at 2 to 8°C	Until the expiration date when stored at 2 to 8°C
Analytes	Ethanol Ammonia	Ethanol Ammonia
Differences		
Fill Size	2.5 mL	3 mL
Open Vial Stability	20 days at 2 to 8°C on board Siemens Dimension Vista instrument	20 days at 2 to 8°C

8.0 Statement of Supporting Data

Stability studies have been performed and met the acceptance criteria for Liquichek Ethanol/Ammonia Control (New Device) to determine the open vial and shelf life claims. Product claims are as follows:

Open Vial Stability: 20 days at 2 to 8°C.

Shelf Life Stability 24 Months at 2 to 8°C

9.0 Conclusion

Liquichek Ethanol/Ammonia Control (New Device) is intended to be used for the same intended use as the predicate. It has bovine serum albumin matrix and performs similarly as the predicate device

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 20, 2012

Bio-Rad Laboratories
c/o Suzanne Parsons
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k123198
Trade/Device Name: Liquichek Ethanol/Ammonia Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: Class I, reserved
Product Code: JJY
Dated: October 8, 2012
Received: October 25, 2012

Dear Ms. Suzanne Parsons:

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 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); 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 regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k123198

Device Name: **Liquichek Ethanol/Ammonia Control**

Indications for Use:

Liquichek Ethanol/Ammonia Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

The following analytes are included in the package insert:

1. **Ethanol**
2. **Ammonia**

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung Chan

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123198