K121794

Summary of Safety and Effectiveness

Liquichek Urine Chemistry Control

1.0 **Submitter**

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JUL 11 2012

Contact Person

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Date of Summary Preparation

June 15th, 2012

2.0 **Device Identification**

Product Trade Name:	Liquichek Urine Chemistry 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**

Liquichek Urine Chemistry Control
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K020817

4.0 **Description of Device**

Liquichek Urine Chemistry Control is prepared from human urine with added constituents of human and animal origin, chemicals, preservatives and stabilizers. The control is provided in liquid form for convenience

5.0 **Value Assignment**

The mean values and the corresponding ±3SD ranges printed in the 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.

6.0 Intended Use

Liquichek Urine Chemistry Control is intended for use as an assayed quality control urine to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

7.0 Comparison of the new device with the Predicate Device

Liquichek Urine Chemistry Control claims substantial equivalence to the Liquichek Urine Chemistry Control currently in commercial distribution (K020817). 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 Urine Chemistry Control *(New Device)*	Liquichek Urine Chemistry Control *(Predicate Device, K020817)*
	Similarities	
Intended Use	Liquichek Urine Chemistry Control is intended for use as an assayed quality control urine to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.	Liquichek Urine Chemistry Control is intended for use as an assayed quality control urine to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.
Matrix	Human Urine	Human Urine
Form	Liquid	Liquid
Open Vial Stability	30 days at 2°C to 8 °C	30 days at 2°C to 8 °C
Storage unopened (Shelf life)	2 to 8°C until expiration date	2 to 8°C until expiration date
	Differences	
Fill Volume	For Level 1 and 2 – 12 x 2.5 mL For Bilevel MiniPak - 2 x 2.5 mL	For Level 1 and 2 – 12 x 10 mL For Bilevel MiniPak - 2 x 10 mL
Analytes	**Contains:** Amylase Calcium Chloride Creatinine Glucose Magnesium Micoalbumin (Albumin) Phosphorus Potassium Protein, Total Sodium Urea Nitrogen (BUN) Uric Acid **Does not contain** Urea Cortisol Osmolality pH Pregnancy Specific Gravity	**Contains:** Amylase Calcium Chloride Cortisol Creatinine Glucose Magnesium Micoalbumin (Albumin) Osmolality Phosphorus pH Pregnancy Potassium Protein, Total Specific Gravity Sodium Urea Urea Nitrogen (BUN) Uric Acid

8.0 Statement of Supporting Data

Stability studies have been performed for Liquichek Urine Chemistry control to determine the open vial and shelf life claims. Product claims are as follows:

Open Vial:	30 days at 2 to 8°C.
Shelf Life Stability	24 Months at 2°C to 8°C

9.0 Conclusion

Liquichek Urine Chemistry control is intended to be used for the same purpose as the predicate device. It has the human urine matrix and performs similarly as the predicate device.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

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

JUL 11 2012

Re: k121794
Trade Name: Liquichek Urine Chemistry Control
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (assayed)
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: June 18, 2012
Received: June 19, 2012

Dear 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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

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

Enclosure

Indications for Use Form

510(k) Number (if known): K121794

Device Name: **Liquichek Urine Chemistry control**

Indications for Use:

Liquichek Urine Chemistry Control is intended for use as an assayed quality control urine to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

The following analytes are listed in the package insert:

- Amylase
- Calcium
- Chloride
- Creatinine
- Glucose
- Magnesium
- Microalbumin (Albumin)
- Phosphorus
- Potassium
- Protein, total
- Sodium
- Urea Nitrogen (BUN)
- Uric Acid

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(K) K121794