Summary of Safety and Effectiveness
Liquichek™ Urinalysis Control

K070848

APR 25 2007

1.0 Submitter

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Contact Person

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Date of Summary Preparation

March 26, 2007

2.0 Device Identification

Product Trade Name:	Liquichek Urinalysis Control
Common Name:	Urinalysis controls (Assayed and Unassayed)
Classifications:	Class I
Product Code:	JJW
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek™ Urinalysis Control
Bio-Rad Laboratories
Irvine, California

Docket Number: K031231

4.0 Description of Device

Liquichek Urinalysis Control is prepared from human urine with added human erythrocytes, simulated leukocytes, constituents of animal origin, pure chemicals, preservatives and stabilizers. The control is provided in liquid form for convenience.

5.0 Statement of Intended Use

Liquichek Urinalysis Control is intended for use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in this package insert.

6.0 Comparison of the new device with the Predicate Device

The new Liquichek Urinalysis Control claims substantial equivalence to the Liquichek Urinalysis Control currently in commercial distribution (K031231).

Liquichek Urinalysis Control claims substantial equivalence to the Liquichek Urinalysis Control currently in commercial distribution (K031231). Both of these controls are manufactured with exactly the same formulation. The only difference between the predicate device and the new Liquichek Urinalysis Control is that new product has claims for color and clarity and the predicate device does not.

Characteristics	**Bio-Rad Liquichek™ Urinalysis Control** (New Device)	**Bio-Rad Liquichek™ Urinalysis Control** (Predicate Device)
	Similarities	
Intended Use	Liquichek Urinalysis Control is intended for use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in this package insert.	Liquichek™ Urinalysis Control is intended for use as an assayed quality control urine to monitor the precision of laboratory dipstick and microscopic testing procedures for analytes listed in this package insert.
Form	Liquid	Liquid
Matrix	Urine	Urine
Storage	2°C to 8°C Until expiration date	2°C to 8°C Until expiration date
Open Vial	30 days at room temperature (18-25° C)	30 days at room temperature (18-25° C)
Preservatives	5-chloro-2-methyl-2H-isothiazol-3-one	5-chloro-2-methyl-2H-isothiazol-3-one
Squeezer Caps	Approved for Use	Approved for Use
	Differences	
Analytes	Same analytes as the predicate device with the additional claims for color and clarity.	Does not have claims for color and clarity

7.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek Urinalysis Control. Product claims are as follows:

7.1 Open vial: Once the control is opened and stored tightly capped, all analytes will be stable for 30 days at room temperature (18 to 25°C).

7.2 Shelf Life: 30 months when stored at 2 to 8°C.

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

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Bio-Rad Laboratories
c/o Ms. Suzanne Parsons
Regulatory Affairs Representative
9500 Jeronimo Road
Irvine, California 92618-2017

APR 25 2007

Re: k070848
Trade/Device Name: Liquichek™ Urinalysis Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJW
Dated: March 26, 2007
Received: March 28, 2007

Dear Ms. 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); 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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070848

Device Name: **Liquichek™ Urinalysis Control**

Indications For Use: **Liquichek Urinalysis Control is intended for use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in the package insert.**

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)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K070848