JUN 1 8 2003

K03/231

Summary of Safety and Effectiveness
Liquichek™ Urinalysis Control

1.0 Submitter

Bio-Rad Laboratories
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Contact Person

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Date of Summary Preparation

March 14, 2003

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: K965171

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 (K965171).

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

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
	Differences	
Open Vial	30 days at 2 to 8° C or 7 days at room temperature (18-25° C)	30 days at 2-8° C or 10 immersions whichever comes first or 7 days at room temperature (18 to 25° C) or 10 immersions whichever comes first.
Preservatives	5-chloro-2-methyl-2H-isothiazol-3-one	Level 2 contains Sodium Azide.
Squeezer Caps	Approved for Use	Not approved for use
Analytes	Same analytes as the predicate device with the additional claims for Creatinine and Protein-Creatinine Ratio.	Does not have claims for Creatinine or Protein-Creatinine Ratio.

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 2 to 8°C, or 7 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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

JUN 1 8 2003

Re: k031231
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: April 14, 2003
Received: April 29, 2003

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 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

510 (k) Number (if known): K031231

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 this package insert.

Jean Cooper

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031231

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use _____