K050687

APR 29 2005

Summary of Safety and Effectiveness
Liquichek Urine Toxicology Control (Level C1)

1.0 Submitter

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Date of Summary Preparation

March 9, 2005

2.0 Device Identification

Product Trade Name:	Liquichek Urine Toxicology Control
Common Name:	Drug Mixture Control
Classifications:	Class I
Product Code:	DIF
Regulation Number:	21 CFR 862.3280

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek Urine Toxicology Control

Bio-Rad Laboratories
Irvine, California

Docket Number: K033404

4.0 Description of Device

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

5.0 Statement of Intended Use

Liquichek Urine Toxicology Control is intended for use as quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.

6.0 Comparison of the new device with the Predicate Device

The new Liquichek Urine Toxicology Control (Level C1) claims substantial equivalence to the Liquichek Urine Toxicology Control (Level C1) currently in commercial distribution (K033404). The new Liquichek Urine Toxicology Control contains MDMA, MDA and MDEA and the predicate device does not.

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

Characteristics	Bio-Rad Liquichek Urine Toxicology Control (Level C1) (Predicate Device K033404)	Bio-Rad Liquichek Urine Toxicology Control (Level C1) (New Device)
Similarities		
Intended Use	Liquichek Urine Toxicology Control is intended for use as quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.	Liquichek Urine Toxicology Control is intended for use as quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.
Form	Liquid	Liquid
Matrix	Urine	Urine
Storage (Unopened)	2-8°C until expiration date	2-8°C until expiration date
Open Vial	30 days at 2-8°C	30 days at 2-8°C
Differences		
Drugs	Contains: d-Amphetamine d-Methamphetamine Secobarbital Amobarbital Butalbital Pentobarbital Phenobarbital Nordiazepam α-hydroxyalprazolam 11-Nor-Δ-9-THC-9-COOH Benzoylecgonine Ethanol LSD Methadone Methaqualone Morphine-3-β-D-glucuronide Codeine Phencyclidine Norpropoxyphene Creatinine Specific Gravity pH Does not contain: MDMA MDA MDEA	Contains: d-Amphetamine d-Methamphetamine Secobarbital Amobarbital Butalbital Pentobarbital Phenobarbital Nordiazepam α -hydroxyalprazolam 11-Nor-Δ-9-THC-9-COOH Benzoylecgonine Ethanol LSD Methadone Methaqualone Morphine-3-β-D-glucuronide Codeine Phencyclidine Norpropoxyphene Creatinine Specific Gravity pH MDMA MDA MDEA

7.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek Urine Toxicology Control (Level C1). Product claims are as follows:

7.1 Open vial: 30 days at 2-8°C.

7.2 Shelf Life: Three years stored at 2-8°C

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 9 2005

Ms. Suzanne S. Parsons
Regulatory Affairs Specialist
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine CA 92618-2017

Re: k050682
Trade/Device Name: Liquichek Urine Toxicology Control (Level C1)
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical toxicology control material
Regulatory Class: Class I
Product Code: DIF
Dated: March 10, 2005
Received: March 16, 2005

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 (240)276-0484. 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/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, 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):

Device Name: **Liquichek Urine Toxicology Control (Level C1)**

Indications For Use: **Liquichek Urine Toxicology Control is intended for use as quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.**

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)
Division of Clinical Laboratory Devices
510(k) Number K050682