K052053

Summary of Safety and Effectiveness
Liquichek Qualitative Urine Toxicology Control

AUG 9 - 2005

1.0 Submitter

Bio-Rad Laboratories
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Contact Person

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Date of Summary Preparation

July 25, 2005

2.0 Device Identification

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

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek Qualitative Urine Toxicology Control
Bio-Rad Laboratories
Irvine, California

Docket Number: K033366

4.0 Description of Device

Liquichek Qualitative Urine Toxicology Controls are 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 Qualitative Urine Toxicology Control is intended for use as an assayed quality control urine to monitor the performance of laboratory procedures for qualitative urine toxicology.

6.0 Comparison of the new device with the Predicate Device

The new Liquichek Qualitative Urine Toxicology Control contains Oxycodone, and the currently marketed Liquichek Qualitative Urine Toxicology Control (K033366) to which substantial equivalence is claimed, does not contain Oxycodone.

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

Characteristics	Bio-Rad Liquichek Qualitative Urine Toxicology Control (New Device)	Bio-Rad Liquichek Qualitative Urine Toxicology Control (Predicate Device K001973)
Similarities		
Intended Use	Liquichek Qualitative Urine Toxicology Control is intended for use as an assayed quality control urine to monitor the performance of laboratory procedures for qualitative urine toxicology.	Liquichek Qualitative Urine Toxicology Control is intended for use as an assayed quality control urine to monitor the performance of laboratory procedures for qualitative urine toxicology.
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 to 8°C or 18 to 25°C	30 days at 2 to 8°C or 18 to 25°C
Differences		
Drugs	Same as the predicate device with addition of Oxycodone	Contain: Amphetamines Barbiturates Benzodiazepines Benzoylecgonine Cannabinoids Cocaine d-Amphetamine d-Methamphetamine Ethanol LSD MDMA (Ecstasy) Methadone Methaqualone Morphine (Free) Nordiazepam Nortriptyline Opiates Oxazepam Phencyclidine Propoxyphene Secobarbital Tricyclic Antidepressants (TCA) Do not contain: Oxycodone

2.0 STATEMENT OF SUPPORTING DATA

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

2.1 Open vial: All analytes will be stable for 30 days when stored tightly capped at 2 to 8°C or 18 to 25°C.

2.2 Shelf Life: 3 Years at 2 to 8°C

2.3 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
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 - 2005

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

Re: k052053
Trade/Device Name: Liquichek Qualitative Urine Toxicology Control
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical Toxicology control material
Regulatory Class: Class I
Product Code: DIF
Dated: July 25, 2005
Received: July 29, 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 (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,

for Carol C. Benson, M.A.
Acting 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): K052053

Device Name: **Liquichek Qualitative Urine Toxicology Control**

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

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 K052053