



**Bio-Rad
Laboratories**

*Diagnostics Group
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Irvine, California 92618-2017
Telephone: (714) 598-1200*

K981590

JUN 10 1998

510(k) Summary

Submitter

Bio-Rad Laboratories, ECS Division
9500 Jeronimo Road
Irvine, CA 92618
(949)598-1285
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Contact Person

Elizabeth Platt

Date of Summary Preparation

April 30, 1998

Device (Trade & Common Name)

Liquichek Urine Toxicology Control

Classification Name

Class I, CFR 862.3280: Drug Mixture Control
91DIF

Devices to Which Substantial Equivalence is Claimed

Liquid Drugs of Abuse Controls
Medical Analysis Systems, Camarillo, California
K903430

Statement of Intended Use

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

Description of the Device

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



This product contains 0.1% sodium azide as a preservative.

Statement of How Technological Characteristics Compare to Substantial Equivalence Device

A table is provided below comparing the similarities between the Bio-Rad Liquichek Urine Toxicology Control and the devices to which substantial equivalence is claimed.

	Bio-Rad Liquichek Urine Toxicology Control	Liquid Drugs of Abuse Controls Medical Analysis Systems
Intended Use	A quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.	A consistent test sample of known concentration for monitoring assay conditions in quantitative and qualitative analysis of patient urine specimens for drug and drug metabolites.
Levels	<p>Level C1 = Drugs added at concentrations approximately 60% below confirmatory cutoffs or at LOQ</p> <p>Level C2 = Drugs added at concentrations 20-25% below confirmatory cutoffs</p> <p>Level C3 = Drugs added at concentrations 20-25% above confirmatory cutoffs</p> <p>Level C4 = Elevated confirmatory control</p>	<p>Level G2 = 20-25% below GC/MS cutoff</p> <p>Level G3 = 20-25% above GC/MS cutoff</p> <p>Level G4 = Elevated GC/MS</p>
Form	Liquid	Liquid
Open Vial Claim	30 Days at 2-8°C	30 Days at 2-8°C
Matrix	Human Urine	Human Urine
Storage	2-8°C	2-8°C



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 10 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Elizabeth Platt
Acting Regulatory Affairs/Quality Assurance
Bio Rad Laboratories
9500 Jeronimo Road
Irvine, California 92618-2017

Re: K981590
Liquichek Urine Toxicology Control
Regulatory Class: I
Product Code: DIF
Dated: April 30, 1998
Received: May 4, 1998

Dear Ms. Platt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

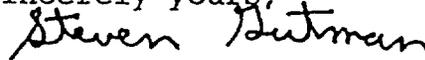
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K981590

Device Name: Liquichek Urine Toxicology Control

Indications for Use:

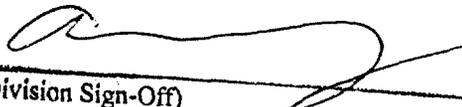
Liquichek Urine Toxicology Control is intended for use as a quality control urine to monitor the performance of laboratory urine toxicology confirmatory procedures.

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

(Concurrence of CDRH, Office of Device Evaluation)

Prescription Use

OR Over-The Counter Use


(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K981590