K971691

BIO-RAD **Bio-Rad Laboratories**

ECS Division
3726 E. Miraloma Avenue
Anaheim, CA 92806
Telephone (714) 630-6400
Toll Free (800) 854-6737

510(k) Summary

MAY 30 1997

Submitter
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3726 E. Miraloma Avenue
Anaheim, CA 92806
(714)630-6400
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Contact Person
Elizabeth Platt

Date of Summary Preparation
February 7, 1997

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.

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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 screening 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	Level S1 = Drugs added at concentrations 20-25% below immunoassay cutoff Level S2 = Drugs added at concentrations 20-25% above immunoassay cutoff Level S3 = Elevated immunoassay	Level 2 = 20-25% below immunoassay cutoff Level 3 = 20-25% above immunoassay cutoff Level 4 = Elevated immunoassay
Form	Liquid	Liquid
Matrix	Human Urine	Human Urine
Storage	2-8°C	2-8°C
Open Vial Claim	30 Days at 2-8°C	30 Days at 2-8°C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 30 1997

Elizabeth Platt
Staff Regulatory Affairs Representative
Bio-Rad Laboratories
3726 E. Miraloma Avenue
Anaheim, California 92806

Re: K971691
Liquichek Urine Toxicology Control - Level S1, S2, S3
Regulatory Class: I
Product Code: DIF
Dated: April 16, 1997
Received: May 7, 1997

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 (Premarket 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 premarket 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.

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 Gutman

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: _____

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 screening procedures.

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

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(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 K971691