

JUN 24 1997

K972174



**Bio-Rad  
Laboratories**

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

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## 510(k) Summary

### Submitter

Bio-Rad Laboratories, ECS Division  
3726 E. Miraloma Avenue  
Anaheim, CA 92806  
(714)630-6400  
Fax (714)666-1383

### Contact Person

Elizabeth Platt

### Date of Summary Preparation

June 5, 1997

### Device (Trade & Common Name)

Lyphochek REMEDi Control

### Classification Name

Class I, CFR 862.3280: Drug Mixture Control  
91DIF

### Devices to Which Substantial Equivalence is Claimed

Lyphochek Urine Toxicology Control  
Bio-Rad Laboratories, ECS Division  
Anaheim, CA  
K881989

### Statement of Intended Use

Lyphochek REMEDi Control is intended for use as a quality control urine for the REMEDi HS Drug Profiling System.



Description of the Device

Lyphocek REMEDi Control is prepared from human urine with added therapeutic drugs and drugs of abuse. The control is provided in lyophilized form for increased stability.

Statement of How Technological Characteristics Compare to Substantial Equivalence Device

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

	Bio-Rad Laboratories Lyphocek REMEDi Control	Bio-Rad Laboratories Lyphocek Urine Toxicology Control
Intended Use	Lyphocek REMEDi Control is intended for use as a quality control urine for the REMEDi HS Drug Profiling System.	Lyphocek Urine Toxicology Control is intended for use as a quality control urine to monitor the performance of an individual laboratory's broad-scren testing of drugs of abuse in urine.
Levels	Two	One
Form	Lyophilized	Lyophilized
Open Vial Claim	30 Days at 2-8°C	10 Days at 2-8°C
Matrix	Human Urine	Human Urine
Storage	2-8°C	2-8°C



JUN 24 1997

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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

Re: K972174  
Lyphochek REMEDi Control  
Regulatory Class: II  
Product Code: DIF  
Dated: June 5, 1997  
Received: June 9, 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.

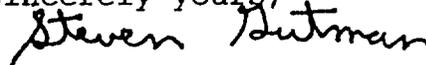
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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: \_\_\_\_\_

Device Name: Lyphochek REMEDi Control

Indications for Use:

Lyphochek REMEDi Control is intended for use as a quality control urine for the REMEDi HS Drug Profiling System.

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

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(Concurrence of CDRH, Office of Device Evaluation)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number         K 972174        

Prescription Use     ✓    

OR Over-The Counter Use \_\_\_\_\_