K971952

BIO-RAD **Bio-Rad Laboratories**

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

JUN 16 1997

510(k) Summary

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

Date of Summary Preparation
May 27, 1997

Device (Trade & Common Name)
Lyphochek Hypertension Markers Control

Classification Name
Class I, 75JJY
CFR 862.1660: Quality Control Material (Assayed and Unassayed)

Devices to Which Substantial Equivalence is Claimed
Renin Control
Ciba Corning Diagnostics
Medfield, MA

Statement of Intended Use
Lyphochek Hypertension Markers Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

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Description of the Device

Lyphochek Hypertension Markers Control is prepared from defibrinated human plasma with added constituents of human origin and pure chemicals. The control is provided in lyophilized form for increased stability.

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 Lyphochek Hypertension Markers Control and the device to which substantial equivalence is claimed.

	Bio-Rad Lyphochek Hypertension Markers Control	Ciba Corning Diagnostics Renin Control
Intended Use	An assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	To monitor the precision and the accuracy of clinical chemistry test procedures which analyze renal and adrenal function.
Levels	Three	Two
Form	lyophilized	lyophilized
Open Vial Claim	21 Days at 2-8°C with the exception of ACTH which should be assayed immediately after reconstitution	8 hours at 2-8°C
Matrix	defibrinated human plasma	human plasma
Storage	2-8°C	2-8°C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 16 1997

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

Re: K971952
Lyphochek Hypertension Markers Control
Regulatory Class: I
Product Code: JJY
Dated: May 27, 1997
Received: May 28, 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: 971952

Device Name: Lyphochek Hypertension Markers Control

Indications for Use:

Lyphochek Hypertension Markers Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number 971952

(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 _____