

K981532



MAY 12 1998

**Bio-Rad  
Laboratories**

Diagnostics Group  
9500 Jeronimo Road  
Irvine, California 92618-2017  
Telephone: (714) 598-1200

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## 510(k) Summary

### Submitter

Bio-Rad Laboratories  
9500 Jeronimo Road  
Irvine, CA  
(949)598-1285  
Fax (949)598-1555

### Contact Person

Elizabeth Platt

### Date of Summary Preparation

April 28, 1998

### Device (Trade & Common Name)

Lyphochek Immunoassay Plus Control

### Classification Name

CFR 862.1660: Quality Control Material  
(Assayed and Unassayed)

### Devices to Which Substantial Equivalence is Claimed

Lyphochek Immunoassay Plus Control  
Bio-Rad Laboratories, Irvine, CA  
K891475

### Statement of Intended Use

Lyphochek Immunoassay Plus 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.

Description of the Device

Lyphochek Immunoassay Plus Control is prepared from human serum, with added constituents of human origin, pure chemicals and therapeutic drugs. 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 Lyphochek Immunoassay Plus Control and the device to which substantial equivalence is claimed.

	Bio-Rad Lyphochek Immunoassay Plus Control	Bio-Rad Lyphochek Immunoassay Plus Control <b>(new submission)</b>
Intended Use	An assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	An assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Lyophilized	Lyophilized
Matrix	Human Serum	Human Serum
Storage	2-8°C	2-8°C
Reconstituted Stability Claim	7 days at 2-8°C with the following exceptions: (1) C-Peptide, Folate and PSA are stable for 3 days after reconstitution, (2) ACTH, Calcitonin and Gastrin should be assayed immediately after reconstitution.	7 days at 2-8°C with the following exceptions: (1) C-Peptide, Folate and PSA are stable for 3 days after reconstitution, (2) ACTH, Calcitonin and Gastrin should be assayed immediately after reconstitution.
Differences	Current product does not have claims for the following: Total Estrogens, Flecainide, IgA, IgG, IgM, Iron, TIBC, Netilmicin, SHBG.	Product has added claims for the following: Total Estrogens, Flecainide, IgA, IgG, IgM, Iron, TIBC, Netilmicin, SHBG.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

MAY 12 1998

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

Re: K981532  
Lyphochek Immunoassay Plus Control  
Regulatory Class: I  
Product Code: JJY  
Dated: April 28, 1998  
Received: April 29, 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 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: Lyphochek Immunoassay Plus Control

Indications for Use:

Lyphochek Immunoassay Plus 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.

(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

*Veronica J. Calver for A. Montgomery*

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K98153a