# Summary of Safety and Effectiveness
# Lyphochek® Whole Blood Control

## 1.0 Submitter

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### Contact Person

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### Date of Summary Preparation

June 18, 2002

## 2.0 Device Identification

| | |
|---|---|
| Product Trade Name: | Lyphochek® Whole Blood Control |
| Common Name: | Multi-Analyte Controls, (Assayed and unassayed) |
| Classifications: | Class I |
| Product Code: | JJY |
| Regulation Number: | 21 CFR 862.1660 |

## 3.0 Device to Which Substantial Equivalence is Claimed

Lyphochek® Whole Blood Control
Bio-Rad Laboratories
Irvine, California

Docket Number: K980871

## 4.0 Description of Device

Lyphochek® Whole Blood Control is prepared from human whole blood, with pure chemicals, and stabilizers added. The control is provided in lyophilized form for increased stability.

## 5.0 Statement of Intended Use

Lyphochek® Whole Blood Control are intended for use as an assayed quality control material to monitor the precision of laboratory analytes listed in the package insert.

## 6.0 Comparison of the new device with the Predicate Device

Lyphochek® Whole Blood Control claims substantial equivalence to the Lyphochek® Whole Blood Control currently in commercial distribution (K980871). The new Lyphochek® Whole Blood Control contains Sirolimus and the current product does not.

**Table 1**. Similarities and Differences between new and predicate device.

| Characteristics | Bio Rad Lyphochek® Whole Blood Control (New Device) | Bio Rad Lyphochek® Whole Blood Control (Predicate Device) |
|---|---|---|
| **Similarities** | | |
| **Intended Use** | Lyphochek® Whole Blood Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. | Lyphochek® Whole Blood Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. |
| **Form** | Lyophilized | Lyophilized |
| **Matrix** | Processed Human Whole Blood Lysate | Processed Human Whole Blood Lysate |
| **Differences** | | |
| **Storage (Unopened)** | 2-8°C<br>until expiration date | 2–8°C<br>until expiration date |
| **Reconstituted Vial Claim** | 14 days at 2°C to 8 °C<br>Exception: Red cell folate will be stable for 3 days at 2°C to 8°C. | 14 days at 2°C to 8 °C<br>Exception: Red cell folate will be stable for 3 days at 2°C to 8°C. |
| **After reconstituting and freezing** | After reconstituting and freezing the control, all analytes will be stable for 30 days when stored tightly capped at –10 to -20°C. | After reconstituting and freezing the control, all analytes will be stable for 30 days when stored tightly capped at –10 to -20°C. |
| **Analytes** | Contains: Cyclosporine, Lead, Red Cell Folate, Tacrolimus and Sirolimus. | Contains: Cyclosporine, Lead, Red Cell Folate, Tacrolimus<br>Does not Contain: Sirolimus |

## 7.0 Summary of Performance Data

Stability studies have been performed to determine the reconstituted stability and shelf life for the Lyphochek® Whole Blood Control. Product claims are as follows:

7.1 Reconstituted Stability: Once the control material is reconstituted, all analytes will be stable for 14 days at 2°C to 8 °C with the following the exception: Red Cell Folate will be stable for 3 days at 2°C to 8°C.

7.2 Shelf Life: Three years and three months when stored at 2 to 8 °C

Real time studies will be ongoing to support the shelf life of this product.
All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 16 2002

Ms. Elizabeth Platt
Regulatory Affairs/Quality Assurance Manager
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618

Re: k022041
Trade/Device Name: Lyphochek® Whole Blood Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: June 18, 2002
Received: June 24, 2002

Dear Ms. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/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 (if known): K022041

Device Name: **Lyphochek® Whole Blood Control**

Indications for Use:

**Lyphochek® Whole Blood Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the 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 (ODE)*

Prescription use ✓ or Over-the Counter use _____

Dan Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022041