K020610

APR 2 2 2002

Summary of Safety and Effectiveness
Lyphochek® Whole Blood Metals Control

1.0 Submitter

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
Telephone: (949) 598-1200
Fax: (949) 598-1555

Contact Person

Yvette Lloyd
Senior Regulatory Affairs Specialist
Telephone: (949) 598-1465

Date of Summary Preparation

February 21, 2002

2.0 Device Identification

Product Trade Name:	Lyphochek® Whole Blood Metals Control
Common Name:	Multi-Analyte Controls, (Assayed and unassayed)
Classifications:	Class I
Product Code:	75JJY
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Lyphochek® Whole Blood Metals Control
Bio-Rad Laboratories

510 (k) Number: K984477

4.0 Description of Device

The Lyphochek® Whole Blood Metals Control is a lyophilized control 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

The new Lyphochek® Whole Blood Metals Control is an assayed control used for monitoring the precision of laboratory testing procedures for the analytes listed in the package insert.

6.0 Comparison of the new device with the Predicate Device

This control is substantially equivalent to the following quality control material for whole blood metals analysis that is currently in the market:

Lyphochek® Whole Blood Metals Control
Bio-Rad Laboratories

510 (k) Number: K984477

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

Characteristics	Lyphochek® Whole Blood Metals Control (New Device)	Lyphochek® Whole Blood Metals Control (Predicate Device)
	Similarities	
Intended Use	Lyphochek® Whole Blood Metals Control is intended for use as a assayed quality control to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Lyphochek® Whole Blood Metals Control is intended for use as a assayed quality control to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form	Lyophilized	Lyophilized
Matrix	Human Whole Blood	Human Whole Blood
Storage (Unopened)	2°C to 8°C until expiration date	2°C to 8°C until expiration date

Differences		
Analyte listing	The Lyphochek® Whole Blood Metals Control may be used to test for: • Arsenic • Cadmium • Mercury • Thallium • Red Cell Folate • Lead	The Lyphochek® Whole Blood Metals Control may be used to test for: • Red Cell Folate • Lead
Storage (Opened)	Once opened all analytes will be stable for 14 days with the following exception: red cell folate will be stable for 1 day.	Once opened all analytes will be stable for 14 days with the following exception: red cell folate will be stable for 3 days. [No claims for Arsenic, Cadmium, Mercury, and Thallium].

7.0 Summary of Performance Data

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

7.1 Once the control is reconstituted, all analytes will be stable for 14 days when stored at 2-8°C with the following exception: red cell folate will be stable for 1 day.

7.2 The control is stable for 3 years and 3 months when stored unopened at 2 - 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

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 2 2002

Ms. Yvette Lloyd
Senior Regulatory Affairs Specialist
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k020610
Trade/Device Name: Lyphochek® Whole Blood Metals Control
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical toxicology control material
Regulatory Class: Class I reserved
Product Code: DIE
Dated: February 21, 2002
Received: February 25, 2002

Dear Ms. Lloyd:

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): K020610

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

Indications for Use:

An assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in the package insert.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020610

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use _____