MAR - 4 2004

Summary of Safety and Effectiveness
Lyphochek Assayed Chemistry Control

K040273

1.0 Submitter

Bio-Rad Laboratories
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Contact Person

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Date of Summary Preparation

January 23, 2004

2.0 Device Identification

Product Trade Name:	Lyphochek Assayed Chemistry Control
Common Name:	Quality Control Materials, all kinds (Assayed and Unassayed)
Classifications:	Class I
Product Code:	JJY
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Lyphochek Assayed Chemistry Control
Bio-Rad Laboratories
Irvine, California

Docket Number: K874280

4.0 Description of Device

Lyphochek Assayed Chemistry Control is prepared from human serum with added constituents of purified biochemicals (tissue extracts of human and animal origin), chemicals, therapeutic drugs, preservatives and stabilizers. The control is provided in lyophilized form.

5.0 Statement of Intended Use

Lyphochek Assayed Chemistry 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.

6.0 Comparison of the new device with the Predicate Device

Lyphochek Assayed Chemistry Control claims substantial equivalence to the Lyphochek Assayed Chemistry Control currently in commercial distribution (K874280).

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

Characteristics	Bio-Rad Lyphochek Assayed Chemistry Control (New Device)	Bio-Rad Lyphochek Assayed Chemistry Control (Predicate Device K874280)
Similarities		
Intended Use	Lyphochek Assayed Chemistry 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.	Lyphochek Assayed Chemistry 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.
Form	Lyophilized	Lyophilized
Matrix	Serum	Serum
Storage (Unopened)	2-8°C until expiration date	2-8°C until expiration date
After Reconstitution and Freezing	All analytes will be stable for 30 days when stored tightly capped at –10 to –20°C with the following exceptions: Tobramycin will be stable for 20 days	All analytes will be stable for 30 days when stored tightly capped at –10 to –20°C with the following exceptions: Tobramycin will be stable for 20 days
Differences		
Open Vial	7 days at 2 to 8°C with the following exceptions: Acid Phosphatase and Prostatic Acid Phosphatase will be stable for 3 days.	7 days at 2 to 8°C with the following exceptions: Acid Phosphatase, Prostatic Acid Phosphatase and Alkaline Phosphatase will be stable for 3 days.
Analytes	Same as the predicate device with the following exceptions: Does not contain claims for: ▪ Aldolase and Folate Contains claims for the following additional analytes: • Calcium (Ionized) • Copper • Glutamate Dehydrogenase (GLDH) • Globulin • Cholesterol (LDL) • Iron-Binding Capacity, Total (TIBC) • Iron Binding Capacity, Unsaturated (UIBC) ▪ T3 Free • T4 Free • Transferrin • Vitamin B12 • Zinc	Acetaminophen Acid Phosphatase, Total Alanine Aminotransferase (ALT) Albumin Aldolase Alkaline Phosphatase (ALP) αHBDH Alpha-1-Antitrypsin Alpha-Fetoprotein (AFP) Amylase Amylase, Alpha Amylase, Pancreatic Apolipoprotein A-1 Apolipoprotein B Aspartate Aminotransferase (AST/SGOT) Bilirubin, Direct Bilirubin, Indirect Bilirubin, Total C3 Complement C4 Complement Calcium Carbamazepine Carbon Dioxide (CO2) Carcinoembryonic Antigen (CEA) Ceruloplasmin Chloride Cholesterol, High Density Lipoprotein (HDL) Cholesterol, Total Cholinesterase Cortisol Creatine Kinase (CK) Creatinine Digoxin Folate Gamma Glutamyltransferase (GGT) Gentamicin Globulin Glucose Haptoglobin Immunoglobulin A (IgA) Immunoglobulin G (IgG) Immunoglobulin M (IgM) Iron Lactate (Lactic Acid) Lactate Dehydrogenase (LDH) LAP – Arylamidase Lipase Lithium Magnesium Osmolality Phenobarbital Phenytoin Phosphorus Potassium Prostate Specific Antigen (PSA) Prostatic Acid Phosphatase (PAP) Protein Electrophoresis Protein, Total Salicylate Sodium T3 Total T3 Uptake T4 Total Theophylline Thyroid Stimulating Hormone (TSH) Thyroxine Binding Globulin (TBG) Tobramycin Transferrin Triglycerides Urea Urea Nitrogen Uric Acid Valproic Acid Vancomycin

7.0 Statement of Supporting Data

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

7.1 Open vial: All analytes will be stable for 7 days at 2 to 8°C with the following exceptions: Acid Phosphatase and Prostatic Acid Phosphatase will be stable for 3 days.

7.2 After reconstitution and freezing: All analytes will be stable for 30 days when stored at –10 to –20°C with the exception of Tobramycin which will be stable for 20 days.

7.3 Shelf Life: 3 Years + 4 Months at 2 to 8°C

7.4 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

MAR - 4 2004

Ms. Elizabeth Platt
Regulatory Affairs Manager/Quality Assurance
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k040273
Trade/Device Name: Lypochek Assayed Chemistry Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: January 23, 2004
Received: February 5, 2004

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K040273

Device Name: **Lyphochek Assayed Chemistry Control**

Indications for Use:

For use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use X or Over-the Counter use_____

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040273