JAN 2 2 2014

510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirement 21 CFR 807.92

Lyphochek Specialty Immunoassay Control
510(k) Number: k133960

1.0 **Submitter**

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Regulatory Affairs Manager
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Date of Summary Preparation

January 10, 2014

2.0 **Device Identification**

Product Trade Name:	Lyphochek Specialty Immunoassay Control
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Classifications:	Class I reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 **Device to Which Substantial Equivalence is Claimed**

Liquichek Specialty Immunoassay Control

510(k) Number: k043108

4.0 Intended Use

Lyphochek Specialty Immunoassay 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.

5.0 Description of Device

Lyphochek Specialty Immunoassay Control is prepared from human serum with added chemicals, stabilizers, and preservatives. The control is provided in lyophilized form and contains the following analytes:

- Erythropoietin (EPO)
- Procalcitonin
- Intact Parathyroid Hormone (Intact PTH)
- Sex Hormone Binding Globulin (SHBG)
- Vitamin D

Each human donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.

Product Configurations

Description	Configuration
Lyphochek Specialty Immunoassay Control, Level 1	6 x 2 mL
Lyphochek Specialty Immunoassay Control, Level 2	6 x 2 mL
Lyphochek Specialty Immunoassay Control, Level 3	6 x 2 mL
Lyphochek Specialty Immunoassay Control, Trilevel MiniPak	3 x 2 mL

6.0 Value Assignment

The mean values and the corresponding ±3SD ranges indicated on the control value sheet provided for Lyphockek Specialty Control were derived from replicate analyses and are specific for each lot of product. The tests listed on the control value sheet were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of the lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

7.0 Comparison of the new device with the Predicate Device

Lyphochek Specialty Immunoassay Control claims substantial equivalence to the Liquichek Specialty Immunoassay Control currently in commercial distribution (k043108). The table below contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Similarities and Differences between new and predicate device.

Characteristics	Lyphochek Specialty Immunoassay Control *(Candidate Device)*	Liquichek Specialty Immunoassay Control *(Predicate Device, k043108)*
	Similarities	
Intended Use	Lyphochek Specialty Immunoassay 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.	Liquichek Specialty Immunoassay Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.
Matrix	Human Serum	Human Serum
Preservatives	Contains preservatives	Contains preservatives
Stabilizers	Contains stabilizers	Contains stabilizers
	Differences	
Form	Lyophilized	Liquid
Storage unopened (Shelf life)	2 to 8°C until expiration date	-20 to -70°C until expiration date
Reconstituted / Opened Vial Stability	30 days at 2°C to 8 °C Except: ➢ Intact PTH: 12 days at 2°C to 8 °C ➢ Procalcitonin: 3 days at 2°C to 8 °C	30 days at 2°C to 8 °C Except: ➢ Intact PTH: 23 days at 2 to 8°C
Fill Volume	2 mL MiniPak: Trilevel - 3 x 2 mL	5 mL MiniPak: Four level - 4 x 5 mL
Frozen Aliquot stability	All analytes : 30 days at -20°C to -70°C	No Claim
Analytes	**Contains:** • Erythropoietin (EPO) • Procalcitonin • Intact Parathyroid Hormone (Intact PTH) • Sex Hormone Binding Globulin (SHBG) • Vitamin D **Does not contain:** • Anti-Thyroglobulin (Anti-Tg) • Anti-Thyroperoxidase (Anti-TPO) • C-Peptide • Insulin Like Growth Factor I (IGF-I) • Osteocalcin	**Contains:** • Anti-Thyroglobulin (Anti-Tg) • Anti-Thyroperoxidase (Anti-TPO) • C-Peptide • Insulin Like Growth Factor I (IGF-I) • Intact Parathyroid Hormone (Intact PTH) • 25-OH Vitamin D • Osteocalcin • Erythropoietin (EPO) **Does not contain:** • Procalcitonin • Sex Hormone Binding Globulin (SHBG)

8.0 Stability

Real time stability studies were performed to establish reconstituted/open vial stability and frozen aliquot stability. Accelerated stability studies were performed for establishing the shelf life stability. The stabilities for Lyphochek Specialty Immunoassay Control are as follows:

Reconstituted Vial Stability:	Intact Parathyroid Hormone (Intact PTH): 12 days at 2°C to 8 °C Procalcitonin: 3 days at 2°C to 8 °C Erythropoietin (EPO), Sex Hormone Binding Globulin (SHBG) and Vitamin D: 30 days at 2 to 8°C
Frozen Aliquot Stability:	30 days at -20°C to -70°C
Shelf Life Stability:	36 Months at 2 to 8°C

9.0 Conclusion

Based on the performance characteristics indicated above, Lyphochek Specialty Immunoassay Control is substantially equivalent to the predicate device (k043108).

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 22, 2014

BIO-RAD LABORATORIES
SUZANNE PARSONS
REGULATORY AFFAIRS MANAGER
9500 JERONIMO RD.
IRVINE CA 92618-2017

Re: K133960
Trade/Device Name: Lyphochek Specialty Immunoassay Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I Reserved
Product Code: JJY
Dated: December 20, 2013
Received: December 24, 2013

Dear Ms. Parsons:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133960

Device Name
Lyphochek Specialty Immunoassay Control

Indications for Use *(Describe)*
Lyphochek Specialty Immunoassay 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung Chan -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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