510(k) Summary

Liquichek Immunology Control

APR 1 2 2013

Submitter

Bio-Rad Laboratories
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Date of Summary Preparation

March 6, 2013

1.0 **Submission Number**

K130761

2.0 **Device Identification**

Product Trade Name:	Liquichek Immunology Control
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Review Panel:	Clinical Chemistry and Clinical Toxicology Devices
Classifications:	Class I, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 **Intended Use**

Liquichek Immunology 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.

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

Liquichek Immunology Control
Bio-Rad Laboratories
Irvine, California
510 (k) Number: K022991

5.0 **Description of Device**

Liquichek Immunology Control is prepared from defibrinated human plasma with added serum proteins, preservatives and stabilizers. The control is provided in liquid form for convenience.

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.

Table 1: Product Configuration

Level	Configuration
Level 1	6 x 2.5 mL
Level 2	6 x 2.5 mL
Level 3	6 x 2.5 mL
Trilevel MiniPak	3 x 2.5 (1 per level) mL

6.0 Comparison of the new device with the Predicate Device

The new Liquichek Immunology Control claims substantial equivalence to the Liquichek Immunology Control currently in commercial distribution (K022991). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Table 2: Similarities and Differences between the new and predicate device

Characteristics	Liquichek Immunology Control *(New Device)*	Liquichek Immunology Control *(Predicate Device, K022991)*
	Similarities	
Intended Use	Liquichek Immunology 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.	Liquichek Immunology 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.
Matrix	Defibrinated Human Serum	Defibrinated Human Serum
Form	Liquid	Liquid
Analytes	**Contains:** • Albumin • Alpha-1-Acid Glycoprotein • Alpha-1-Antitrypsin • Alpha-2-Macroglobulin • Antistreptolysin O • Apolipoprotein A-1 • Apolipoprotein B • Beta-2-Microglobulin • C1 Inhibitor • C-Reactive Protein (CRP) • Ceruloplasmin • Complement C3 • Complement C4 • Cystatin C • Ferritin • Haptoglobin • IgG1 Subclass • IgG2 Subclass • IgG3 Subclass • IgG4 Subclass • Immunoglobulin A • Immunoglobulin E • Immunoglobulin G • Immunoglobulin M • Kappa Light Chain • Lambda Light Chain • Prealbumin • Protein, Total • Retinol Binding Protein	**Contains:** • Albumin • Alpha-1-Acid Glycoprotein • Alpha-1-Antitrypsin • Alpha-2-Macroglobulin • Antistreptolysin O • Apolipoprotein A-1 • Apolipoprotein B • Beta-2-Microglobulin • C1 Inhibitor • C-Reactive Protein (CRP) • Ceruloplasmin • Complement C3 • Complement C4 • Cystatin C • Ferritin • Haptoglobin • IgG1 Subclass • IgG2 Subclass • IgG3 Subclass • IgG4 Subclass • Immunoglobulin A • Immunoglobulin E • Immunoglobulin G • Immunoglobulin M • Kappa Light Chain • Lambda Light Chain • Prealbumin • Protein, Total • Retinol Binding Protein

	• Rheumatoid Factor • Transferrin	• Rheumatoid Factor • Transferrin
Differences		
Fill Volume	2.5 mL	1mL & 3 mL
Thawed Opened Stability	5 days at 2 to 8°C	30 days at 2 - 8 °C Except for: Beta-2-Microglobulin: 21 days at 2 to 8°C Rheumatoid Factor: 5 days at 2 to 8°C
Thawed Unopened Stability	10 days at 2 to 8°C	90 days at 2 to 8°C Except for: Rheumatoid Factor: 25 days at 2 to 8°C
Storage unopened (Shelf life)	-20°C to -50°C until expiration date	-20°C to -70°C until expiration date
Analytes	**Does not Contain:** • Anti-deoxyribonuclease B • Antithrombin III • CH50 (Total hemolytic Complement) • Lipoprotein (a) • Hemopexin • Properdin Factor B • Soluble Transferrin Receptor (sTfR)	

7.0 Value Assignment

The mean values and the corresponding ±3SD ranges printed in the instructions for use were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this 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.

8.0 Statement of Supporting Data

Real-time stability studies were conducted to establish the thawed stability claims (opened and unopened). Accelerated stability studies were conducted to establish the shelf-life stability claim. Acceptance Criteria were met to support the product claims as follows:

Thawed and Opened:	5 days at 2 to 8°C
Thawed and Unopened:	10 days at 2 to 8°C
Shelf Life Stability:	2 Years at -20 to -50°C

9.0 Proposed Labeling

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

10.0 Conclusion

Based on the performance characteristics indicated above, the Bio-Rad Liquichek Immunology Control is substantially equivalent to the predicate device K022991.

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

Bio-Rad Laboratories
c/o Ms. Suzanne Parsons
9500 Jeronimo Road
IRVINE CA 92618-2017

April 12, 2013

Re: K130761
Trade/Device Name: Liquicheck Immunology Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I
Product Code: JJY
Dated: March 13, 2013
Received: March 20, 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 Part 801); 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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k130761

Device Name: **Liquichek Immunology Control**

Indications for Use:

Liquichek Immunology 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.

Prescription Use X And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130761