K140916

510(k) Summary

Liquichek Cardiac Troponins Control

MAY 06 2014

1.0 **Submitter**

Bio-Rad Laboratories
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Contact Person

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Date of Summary Preparation

May 2, 2014

2.0 **Device Identification**

Product Trade Name:	Liquichek Cardiac Troponins 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 **Device to Which Substantial Equivalence is Claimed**

Liquichek Cardiac Markers Plus Control
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K050537

4.0 **Description of Device**

Liquichek Cardiac Troponins Control is a trilevel liquid control prepared from human protein with added constituents of human and animal origin, stabilizers and preservatives. Liquichek Cardiac Troponins Control is intended for use as an assayed quality control to monitor the precision of Troponin I and Troponin T in laboratory testing procedures.

The human source material 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.

5.0 Value Assignment

The mean values and the corresponding ±3SD ranges printed in this insert were derived from multiple replicate analyses that meet acceptance criteria and are specific for the lot of product. The tests listed 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.

6.0 Intended use

Liquichek Cardiac Troponins 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.

7.0 Comparison of the new device with the Predicate Device

The new Liquichek Cardiac Troponins Control claims substantial equivalence to the Liquichek Cardiac Markers Plus Control currently in commercial distribution (K050537). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

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Table 1: Similarities and Differences between new and predicate device

Characteristics	Bio-Rad Liquichek Cardiac Troponins Control *(New Device)*	Bio-Rad Liquichek Cardiac Markers Plus Control LT *(Predicate Device, K050537)*
Similarities		
Intended Use	This product 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.	This product is intended for use as a quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.
Form	Liquid	Liquid
Aliquot Stability	30 days at -20 to -70 °C	30 days at -20 to -70 °C
Differences		
Matrix	Human Protein	Human Serum
Open vial	25 days at 2 - 8 °C	20 days at 2 - 8 °C with the following exceptions: NT-proBNP: 15 days Troponin I : 10 days BNP: 8 days Troponin T: 4 days
Shelf life	At -20 to -70 °C until the expiration date	At -20 to -70 °C until the expiration date
Analytes	**Contains:** Troponin I Troponin T	**Contains:** Troponin I Troponin T CK Total CK-MB Isoenzyme Digitoxin Homocysteine CRP Myoglobin NT-proBNP BNP
	Does not contain: CK Total CK-MB Isoenzyme Digitoxin Homocysteine CRP Myoglobin NT-proBNP BNP	

8.0 Statement of Supporting Data

Real-time stability studies were conducted to establish the thawed, opened and frozen Aliquot stability claims. 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 Stability:	25 days at 2 to 8 °C
Frozen Aliquot Stability Studies:	30 days at -20°C to -70 °C
Shelf Life Stability:	18 months at -20°C to -70°C

9.0 Conclusion

Based on the performance characteristics indicated above, the Bio-Rad Liquichek Cardiac Troponins Control is substantially equivalent to the predicate device K050537.

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

May 6, 2014

BIO-RAD LABORATORIES
MS SUZANNE PARSONS
9500 JERONIMO RD.
IRVINE CA 92618-2017

Re: K140916
Trade/Device Name: Liquichek Cardiac Troponins Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJY
Dated: April 08, 2014
Received: April 10, 2014

Dear Ms. Suzanne 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 Industry and Consumer Education 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 Industry and Consumer Education 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 **below.**

510(k) Number *(if known)*
k140916

Device Name
Liquichek Cardiac Troponins Control

Indications for Use *(Describe)*
Liquichek Cardiac Troponins 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.

- **Troponin I**
- **Troponin T**

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)*

Ruth A. Chesler -S

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