MAR 1 0 2004

K040277

Summary of Safety and Effectiveness
Liquichek™ Cardiac Markers Control LT

1.0 Submitter

Bio-Rad Laboratories
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Contact Person

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Date of Summary Preparation

February 4, 2004

2.0 Device Identification

Product Trade Name:	Liquichek Cardiac Markers Control LT
Common Name:	Enzyme Controls, (Assayed and unassayed)
Classifications:	Class I
Product Code:	JJT
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Bio-Rad Laboratories
Irvine, California

Liquichek™ Cardiac Markers Control LT
Docket Number: K021498

4.0 Description of Device

Liquichek Cardiac Markers Control LT is prepared from human serum with added constituents of human and animal origin, preservatives and stabilizers. The control is provided in liquid form.

5.0 Statement of Intended Use

Liquichek Cardiac Markers Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory procedures listed in the package insert.

6.0 Preservatives:

The Liquichek Cardiac Markers Control LT does not contain sodium azide as a preservative. It contains a broad-spectrum anti-microbial cocktail as a preservative where the concentration of any one ingredient is less than 0.1%. At this low level, these ingredients are not expected to cause a health hazard to the user. And thus, domestic and international regulations do not require this type of information on the vial or box label.

7.0 Comparison of the new device with the Predicate Device

Liquichek Cardiac Markers Control LT claims substantial equivalence to the Liquichek™ Cardiac Markers Control LT and Liquichek Cardiac Markers Control currently in commercial distribution. The new Liquichek Cardiac Markers Control LT is a four level product (Level 1, 2, 3 and Low Level) and contains NT-proBNP. The current product is a tri-level product and does not contain NT-proBNP.

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

Characteristics	Bio-Rad Liquichek™ Cardiac Markers Control LT (New Device)	Bio-Rad Liquichek™ Cardiac Markers Control LT (Predicate Device K021498)
Similarities		
Intended Use	Liquichek Cardiac Markers Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.	Liquichek Cardiac Markers Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based
Storage (Unopened)	–20°C or colder Until expiration date	–20°C or colder Until expiration date
Differences		
Number of Levels	Levels 1, 2, 3 and Low Level	Levels 1, 2 and 3 (does not contain Low Level)
Open Vial Claim At 2-8°C	All analytes will be stable for 10 days with the following exceptions: NT-proBNP will be stable for 5 days.	Troponin-I, Troponin T and Homocysteine: 10 days. Myoglobin, CK-MB, and Digitoxin: 20 days
Analytes	Contains: NT-proBNP, Myoglobin, CK-MB Isoenzyme, Troponin I, Digitoxin, Troponin T, Homocysteine	Contains: Troponin-I, Troponin T, Myoglobin, CK-MB, Homocysteine and Digitoxin Does not contain: NT-pro BNP

2.0 STATEMENT OF SUPPORTING DATA

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ Cardiac Markers Control LT. Product claims are as follows:

2.1 Open vial: All analytes will be stable for 10 days with the following exceptions: NT-proBNP will be stable for 5 days. .

2.2 Shelf Life: 2 years at -20°C or colder

2.3 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 1 0 2004

Ms. Maria Zeballos
Regulatory Affairs Specialist
Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k040277
Trade/Device Name: Liquichek™ Cardiac Markers Control LT
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: February 4, 2004
Received: February 5, 2004

Dear Ms. Zeballos:

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

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

Indications for Use

510(k) Number (if known): **K040277**

Device Name: **Liquichek™ Cardiac Markers Control LT**

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.

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040277

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)